SOUTH FLORIDA'S ACCESS TO AFFORDABLE PRESCRIPTION DRUGS: COSTS AND BENEFITS OF ALTERNATIVE SOLUTIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

MARCH 10, 2003

Serial No. 108–9

Printed for the use of the Committee on Energy and Commerce

Available via the World Wide Web: http://www.access.gpo.gov/congress/house

U.S. GOVERNMENT PRINTING OFFICE

86–053PS WASHINGTON : 2003

For sale by the Superintendent of Documents, U.S. Government Printing Office
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SOUTH FLORIDA'S ACCESS TO AFFORDABLE PRESCRIPTION DRUGS: COSTS AND BENEFITS OF ALTERNATIVE SOLUTIONS

MONDAY, MARCH 10, 2003

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Aventura, FL.

The subcommittee met, pursuant to notice, at 10 a.m., in the city of Aventura, Florida's Commission Chambers, Second floor, 19200 Country Club Drive, Aventura, Florida, Hon. James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood and Deutsch.

Also present: Representative Engel.

Staff present: Ray Shepherd, majority counsel; Jill Latham, legislative clerk; and Chris Knauer, minority investigator.

Mr. GREENWOOD. This hearing of the U.S. House of Representatives Committee on Energy and Commerce, the Subcommittee on Oversight and Investigations hearing will come to order.

Good morning, we welcome all of you, and thank you for joining us. Before we begin, I would like to ask that those of you who have cellular telephones if you would be so kind as to turn them off or put them on the vibrate setting so we are not interrupted. I would appreciate that. Thank you.

Also like to thank my friend and colleague, Peter Deutsch, for inviting the subcommittee to his district to discuss the important and timely issue of drug prices and the efficacy and safety of some of the alternative methods by which our constituents are currently purchasing drugs.

Last August, the Associated Press reported that a man who rode a U.S. Senate candidate's prescription express, Rx Express, to Canada to buy prescription drugs became sick after ingesting some of the medication he bought while in Canada. Stanley Campa, age 83, of St. Cloud, Minnesota, was rushed to the hospital and almost died when his heart slowed and he passed out after taking Cardizem, a blood pressure medication. According to his doctor, Mr. Campa took the correct drug but in the wrong formulation. Mr. Campa did not receive the correct time release capsule that he usually takes in Minnesota and instead took the pill in tablet form that acts more quickly than the time release capsule. This inadvertent mix-up almost caused his heart to stop.

This incident illustrates two problems. First, the skyrocketing prices of medication and increasingly out of the reach for too many

of our seniors and nearly all those on fixed incomes. Some of the seniors here with us today will testify that they often forego other essentials in order to purchase their necessary medications. In a country as wealthy as ours, we must do better to ensure full access to and the affordability of pharmaceuticals.

I look forward not only to hearing their testimony but also expect that the witnesses on panel three will be able to provide them with instructive information on how to purchase some of their medications at greatly reduced prices or even receive their medications for free.

Second, the incident I referred to illustrates that drugs procured outside the United States can be dangerous for numerous reasons. FDA acknowledges that it cannot monitor or guarantee the safety and effectiveness of drugs purchased outside the closed U.S. distribution system. FDA has warned the public that drugs purchased from foreign countries could be counterfeit. Cheap foreign imitations of FDA-approved drugs that could be sub-potent or super-potent, expired drugs, contaminated drugs or drugs stored under unsafe condition.

After this subcommittee's June 2001 hearing that highlighted the clear and present danger that these drugs posed to the American people, FDA proposed to the Department of Health and Human Services that it allow FDA and Customs to deny entry of all these illegal drugs into the U.S. and return them to sender. To date, Secretary Thompson has not acted on the proposal. I look forward to hearing what actions the FDA has taken to protect our constituents from the dangers of purchasing drugs over the Internet.

Our third panel will discuss how legitimate drugs purchased over the Internet and used without the supervision of a doctor or pharmacist can be just as deadly as counterfeits. In this subcommittee's June 2001 hearing, we heard testimony from Reverend and Mrs. Rode of Illinois who painfully described how their son accidentally overdosed on a mixture of drugs he purchased over the Internet. The drugs turned out to be legitimate and prescribed by a doctor, but their son died as a result of incorrectly mixing a combination of these drugs. This unfortunate incident shows that when drugs are purchased over the Internet, patient care can easily be compromised because there is no interaction with a physician or dispensing pharmacist who are aware of the patient's history and can prevent deadly drug interactions.

In addition to discussing potential safety problems resulting from purchasing cross-border drugs over the Internet, our third panel will also discuss programs by which individuals can receive free or low-cost medications. Hopefully, we can highlight some of these plans and assist the seniors here today to safely purchase these medications while substantially saving money.

I would like to welcome our witnesses here this morning. On panel one, we have private citizens Ms. Resi Coplan. Am I pronouncing that right?

Ms. COPLAN. Resi Coplan.

Mr. GREENWOOD. Resi. Ms. Resi Coplan. Mr. Gene Sweed and the State Director of the American Association of Retired Persons, Mr. Bentley Lipscomb.

On panel two, we will hear from Mr. John Taylor, the Associate Commissioner of Regulatory Affairs for the Food and Drug Administration and Mr. John Taylor, drug inspector for the Bureau of Statewide Pharmaceutical Services of the Florida Department of Health. Yes, you heard me correctly. By a strange coincidence, there are two John Taylors with us this morning. I apologize in advance for the inevitable confusion.

On panel three, we have Dr. Elliott Hahn, chairman and president of Andrx Corporation, Mr. Michael Jackson, executive vice president of the Florida Pharmacy Association, Mr. Carlos A. Ruiz, pharmacy director for Navarro Discount Pharmacy and Mr. Robert N. McEwan, CEO of MEDBANK of Maryland, Incorporated.

And with that, I would yield to our host, the gentleman from Florida, the ranking member of this subcommittee, Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman, and, again, I thank you very much for having this hearing in south Florida but also for the fact of having this hearing. And I just mentioned in this setting that in terms of any substantive committee or subcommittee in Congress, I think the two of us have worked as well as any members, and I think both of us are absolutely committed to finding a solution to what we acknowledge and I think what Americans acknowledge is probably as significant a policy concern as any domestic policy concern that America faces today, and that is the escalating cost and the high cost and access of prescription drugs for seniors. And I think today we will hear testimony that we have heard, in a sense, before but not in this type of setting with specifics. And, honestly, one of the things, it almost has not gotten through to all of our colleagues who might not serve on committees, who might not be concentrating in terms of senior populations, but as severe as the problem is on a day-to-day basis for so many people but also what that has led to.

And I think one of the things we will hear testimony about today is this phenomenon of purchase through the Internet. As this committee has investigated, and hopefully we will gain some insight today, we are trying to get our arms around the extent of it. When we met with the FDA in Washington, the estimates that they gave us that there were 10 million individual purchases of prescription drugs through the Internet in the last year. But they really have no idea if that is an accurate number or not. It could be 30 million, it could be 40 million, it could be even more. And the reality is that people are availing themselves of that I think in many cases because they have no choice. And that is the only option that they see for themselves in terms of their own health care on a personal basis.

And as the chairman pointed out, we have some real concerns because there is anecdotal information, as he has mentioned, but there is no FDA direct regulatory authority. So when people are purchasing, and this is millions of people, there is clearly a question about what they are purchasing. And in a sense, people are making a choice but not a real choice in that activity.

Let me just briefly introduce some of the elected officials who are here today. I thank the city of Aventura for their hospitality for both letting us use the chamber but also for providing my district office as well, the mayor, Jeff Perlow, the commissioner, Harry

Housberg, and the newly elected commissioner, Zev Auerbach. Mayor Sampson from Sunny Isles Beach is here and also the vice-mayor, Norman Edecup and the commissioner from Broward County from the south end of the county, Sue Gunzberger, is here as well.

I can go through a lot of introduction in terms of just the status of the Foreign Drug Act and the FDA 90-day supply policy, but I think I would more anxiously wait for the testimony of the witnesses and be responsive to some of their comments and questions. Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank the gentleman. And that brings us to our first panel, which I have already introduced. We welcome you again and thank you for being with us this morning. This is an investigative hearing of the Oversight and Investigations Subcommittee, and when we hold our hearings it is our practice to take testimony under oath. So I would ask if any of you have any objections to giving your testimony under oath? Okay. You also have the right to be represented by counsel. Sometimes people who come before us are in trouble and need counsel. You probably don't, but do any of you wish to be represented by counsel? Okay. In that case, I am going to ask if you would stand and raise your right hand?

Mr. LIPSCOMB. I can't stand.

Mr. GREENWOOD. Okay. Well, you can just raise your right hand. Do you swear that the testimony you are about to give is the truth, the whole truth and nothing but the truth?

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are under oath, and I guess maybe we will have Mr. Lipscomb go first.

TESTIMONY OF BENTLEY LIPSCOMB, STATE DIRECTOR, AARP; RESI COPLAN; AND GENE SWEED

Mr. LIPSCOMB. Thank you, Mr. Chairman, Congressman Deutsch. I am Bentley Lipscomb, Florida State Director of AARP. I want to thank you, the committee, for your interest in the issue of the high cost of prescription drugs and the difficulties that this poses for older Americans and in particularly older Floridians. AARP appreciates the opportunity to share our perspective on the need to create a Medicare prescription drug benefit for all beneficiaries this year.

For over 30 years, Medicare has provided older and disabled beneficiaries with dependable, affordable, quality health insurance. Florida, for example, has one of the largest beneficiary populations in the Nation. The county where we are having this hearing today has more aging population in it than 19 States. If you take the county immediately to the north and the one immediately to the north of it, the three-county strip from Palm Beach through Dade County, taken together has more aging population than 38 States. You are, in a word, in the most elder-rich section of the United States holding your hearing today.

Throughout my career in the aging community, I have seen first hand how Medicare has made a difference in the lives of older Americans. Medicare has been instrumental in improving the health and life expectancy of beneficiaries in Florida and across our great Nation. Medicare's promise of affordable health care must ex-

tend beyond the current generation of retirees. Now, more than ever, Americans of all ages are looking to Medicare's guaranteed protections as a part of the foundation of their retirement planning. But there is a serious gap in that protection—the absence of a reliable prescription drug coverage.

The practice of medicine has changed dramatically since the Medicare program was created in the sixties. Drug therapies that were not available when Medicare began are now commonly used to prevent and treat virtually every major illness. In many cases, new drugs substitute for or allow patients to avoid more expensive therapies such as hospitalization and surgery. In other cases, drugs facilitate treatment or provide treatment where none existed before, improving the quality and length of life for the patient. As a result, prudent reliance on prescription drugs now goes to the very core of good medical practice.

Given the prominence of drug therapies in the practice of medicine, if Medicare were being designed today, rather than in 1965, not including a prescription drug benefit would be as absurd as not covering doctor visits or hospital stays. That is why ensuring that all beneficiaries have a meaningful, affordable prescription drug program is AARP's top legislative priority. Our members and their families need access to a drug benefit that is affordable, available, dependable, and they need it to happen this year.

AARP is particularly pleased that this subcommittee is examining the issue of the high cost of prescription drugs and the risk of obtaining those drugs outside the United States. And that the Congress has begun to develop its own prescription drug benefit legislation. It is our hope that today's hearing will help increase the visibility of the need for an affordable Medicare prescription drug benefit for all beneficiaries.

As new prescription drugs are becoming available to treat and prevent more and more serious conditions and life-threatening illnesses, reliance on these drugs has become especially significant for our older American population. Ninety percent of Medicare beneficiaries use a prescription drug every day. While older Americans comprise only 12 percent of the U.S. population, they account for 40 percent of prescription drug spending. In fact, after premium payments, prescription drugs account for the single largest component of health care out-of-pocket spending for non-institutionalized Medicare beneficiaries age 65 and older. On average, these beneficiaries spend more out-of-pocket for prescription drugs as for physician care, vision services and medical supplies combined.

The need for a Medicare prescription drug benefit for all beneficiaries continues to escalate. Older and disabled Americans continue to face double-digit increases in their prescription costs. A chronic health problem necessitating new and expensive prescription drugs can quickly deplete a retiree's financial resources. Even a beneficiary who has planned well for his or her retirement may not be prepared for what they are faced with in prescription bills that exceed several hundred dollars to $1,000 a month.

Medicare Plus Choice plans continue to scale back their drug benefits. In Florida, we have seen a major exodus as the plans leave the Medicare program, and many of those that continue to participate have made their benefit less generous, with some cov-

ering only generic drugs. The cost of private Medigap coverage is increasingly unaffordable. While Medigap drug coverage is quite limited, the premiums on these policies can exceed $1,000 a year. State prescription drug assistance programs provide only a limited safety net and are themselves at risk because of the State's current budget crises.

Despite promises of relief, lack of a drug benefit in Medicare persists. Beneficiaries continue to struggle to pay for necessary medications. Some even take desperate and sometimes dangerous measures, as you indicated already, Mr. Chairman. In some instances, beneficiaries do not follow the course of treatment, do not take the prescribed full dosage or take their prescriptions intermittently.

That is why AARP is calling on Congress to pass legislation this year, and it should be a true benefit. Our members have told us that this legislation should ensure all Medicare beneficiaries have access to affordable, meaningful prescription drug coverage; provide stable coverage that beneficiaries can rely on from year to year, and this a particularly poignant point; protect beneficiaries from extraordinary out-of-pocket costs and ensure reasonable cost-sharing; provide lower-income beneficiaries with additional assistance; and not create incentives for employers to drop current retirees' coverages.

AARP members are looking to Congress to fulfill the promise to begin to provide long overdue relief from the devastating costs of prescription drugs. We believe that a prescription drug benefit should be integrated into Medicare in a way that strengthens the program. We do know that a workable prescription drug benefit will require a sizable commitment of Federal dollars. AARP has urged a level of funding that will enable the Congress to design a Medicare drug benefit that will provide real value to beneficiaries. As we learned from last year's debate, more than $400 billion will be needed to create a Medicare prescription drug benefit that our members will find valuable.

Now, as the chairman indicated previously, many of our members are going to either Canada or Mexico or using Internet sites to buy drugs cheaper. We are not supportive of that type of practice, and we find that it is very risky in many instances. But we have to remember why this is an issue: Our members want prescription drugs. In many cases, they have been told by their physicians that it is a matter of life and death in terms of whether they take them. So they either have to go outside the country to get them or they simply can't afford them. Last month, the St. Petersburg, where my office is, instituted passenger ship service between the Port of Tampa and Mexico, and I asked the mayor of St. Petersburg if he was instituting this service so our older citizens could take their cars and go to Mexico and load them up with drugs and come back. Because it has become increasingly prevalent practice to go outside the country to do it, even though those drugs are manufactured in the United States, shipped there and then come back in.

While AARP supported the reimportation amendment that passed the Senate last year, we urge caution because there is serious concern about patient safety and whether the savings are really passed onto consumers. Reimportation, we believe, will continue

to be an issue and one that will need to be addressed until Congress enacts a Medicare benefit for drugs and the President signs it into law.

In conclusion, Mr. Chairman, we believe that creating prescription drug benefit for all beneficiaries is a priority for Floridians, for AARP and for the Nation itself. We pledge to work with you and other Members of Congress to ensure that a Medicare prescription drug bill gains broad bipartisan support and can be enacted into law this year. Thank you very much.

[The prepared statement of Bentley Lipscomb follows:]

PREPARED STATEMENT OF BENTLEY LIPSCOMB, FLORIDA STATE DIRECTOR, AARP

Mr. Chairman and Congressman Deutsch, I am Bentley Lipscomb, Florida state director of AARP. I want to thank you for your interest in the issue of the high cost of prescription drugs and the difficulties older Americans have in paying for needed medications. AARP appreciates this opportunity to share our perspective on the need to create a Medicare prescription drug benefit for all beneficiaries this year.

For over thirty years, Medicare has provided older and disabled beneficiaries with dependable, affordable, quality health insurance. Florida, for example, has one of the largest beneficiary populations in the nation. Throughout my career in the aging community, I have seen first hand how Medicare has made a difference in the lives of older Americans. Medicare has been instrumental in improving the health and life expectancy of beneficiaries in Florida and across the nation. It has also helped to reduce the number of older persons living in poverty.

Medicare's promise of affordable health care extends beyond the current generation of retirees. Now, more than ever, Americans of all ages are looking to Medicare's guaranteed protections as part of the foundation of their retirement planning. But there is a serious gap in Medicare's protection—the absence of reliable prescription drug coverage.

The practice of medicine has changed dramatically since the Medicare program was created. We are now living in a time of amazing breakthroughs in medical research and technology. Among the most striking are the advances in the area of prescription drugs. Drug therapies that were not available when Medicare began are now commonly used to prevent and treat virtually every major illness. In many cases, new drugs substitute for or allow patients to avoid more expensive therapies such as hospitalization and surgery. In other cases, drugs facilitate treatment or provide treatment where none existed before, improving the quality and length of life for the patient. As a result, prudent reliance on prescription drugs now goes to the very core of good medical practice.

Given the prominence of drug therapies in the practice of medicine, if Medicare were being designed today—rather than in 1965—not including a prescription drug benefit would be as absurd as not covering doctor visits or hospital stays. That is why ensuring that all beneficiaries have meaningful, affordable prescription drug coverage is AARP's top legislative priority. Our members and their families need access to a drug benefit that is affordable, available, and dependable, and, they need this to happen this year.

AARP is pleased that this Subcommittee is examining the issue of the high cost of prescription drugs and that the Congress has begun to develop its own prescription drug benefit legislation. It is our hope that today's hearing will help increase the visibility of the need for an affordable Medicare prescription drug benefit for all beneficiaries.

As new prescription drugs are becoming available to treat and even prevent more and more serious conditions and life-threatening illnesses, reliance on these drugs has become especially significant for older Americans. Ninety percent of Medicare beneficiaries use a prescription drug every day. While older Americans comprise only 12 percent of the U.S. population, they account for forty percent of prescription drug spending. In fact, after premium payments, prescription drugs account for the single largest component of health care out-of-pocket spending for non-institutionalized Medicare beneficiaries age 65 and older. On average, these beneficiaries spend more out-of-pocket for prescription drugs as for physician care, vision services, and medical supplies combined.

The need for a Medicare prescription drug benefit for all beneficiaries continues to escalate:

- Older and disabled Americans continue to face double-digit increases in their prescription costs—a chronic health problem necessitating new and expensive prescription drugs can quickly deplete a retiree's financial resources. Even a beneficiary who has planned well for his or her retirement may not be prepared for drug bills that exceed several hundred dollars a month.
- Employer-based retiree health coverage continues to erode—24% of employers with 200 or more employees offered health coverage to their Medicare-age retirees in 2001 compared to 31% in 1997.
- Medicare+Choice plans continue to scale back their drug benefits—In Florida, for example, we have seen many plans leave the Medicare program and many of those that continue to participate have made their benefit less generous with some covering only generic drugs.
- The cost of private Medigap coverage is increasingly unaffordable—while Medigap drug coverage is quite limited, the premiums on these policies exceed $1000 a year.
- State prescription drug assistance programs provide only a limited safety net, and are themselves at risk because of current state budget crises—In Florida, for instance, there are two state pharmaceutical assistance programs. The Sliver Saver Drug program provides assistance of only $80 per person per month and seniors must pass a strict asset test to be eligible.

Despite promises of relief, lack of a drug benefit in Medicare persists. Beneficiaries continue to struggle to pay for necessary medications. Some even take desperate—and sometimes dangerous—measures. For instance, some beneficiaries do not follow a course of treatment, do not take the prescribed full dosage, or take their prescriptions intermittently.

That is why AARP has called on Congress to pass legislation this year.

To be considered a true benefit, our members have told us legislation must:

- Ensure all Medicare beneficiaries have access to affordable, meaningful prescription drug coverage;
- Provide stable coverage that beneficiaries can rely on from year to year;
- Protect beneficiaries from extraordinary out-of-pocket costs and ensure reasonable cost-sharing;
- Provide lower-income beneficiaries with additional assistance; and
- Not create incentives for employers to drop current retiree coverage.

AARP members are looking to Congress to fulfill the promise to begin to provide long-overdue relief from the devastating costs of prescription drugs. We believe that a prescription drug benefit should be integrated into Medicare in a way that strengthens the program.

We know a workable prescription drug benefit will require a sizable commitment of federal dollars. AARP has urged a level of funding that will enable the Congress to design a Medicare drug benefit that will provide real value to beneficiaries. As we learned from last year's debate, more than $400 billion will be needed to create a Medicare prescription drug benefit that our members will find valuable.

In conclusion, we believe that creating prescription drug benefit for all beneficiaries is a priority for Floridians, AARP, and the nation. We want to work with you and other Members of Congress to assure that a Medicare prescription drug bill gains broad bipartisan support and is enacted into law this year.

Mr. GREENWOOD. Thank you, sir. And I think you summarized exactly why Congressman Deutsch asked me to hold this hearing here, because he has expressed to me repeatedly that he wants to make sure that his constituents have affordable prescriptions, and he worries that they don't, but he also has a worry that they make sure that what they get is safe and felt that this would help to underline the vital imperative that Congress move forward quickly to create a prescription drug benefit.

I am going to turn to you, Ms. Coplan, and ask you to testify next, please.

TESTIMONY OF RESI COPLAN

Ms. COPLAN. Okay. Thank you very much. Good morning. My name is Resi Coplan, and I am 67 years old. I was working up until a year ago January when I, unfortunately, had a car accident which exacerbated a problem in my back, giving me a very painful

right hip and right leg and difficulty walking. And the doctors had put me on a medication that was way too strong. It had an anesthetic type of reaction, and I eventually, in July, fell out of bed, fractured my left foot. So I had my right hip and my left foot that I was nursing.

I ended up in the hospital from July 7 until August 20, which is about 6 weeks with time in ICU due to this complication. When I did go back home I had enormous number of medications that I was asked to take, and I had to start to make a plan because there was no way that I was going to be able to afford all of this.

The treatments that I could have had for this back condition to try to eliminate some of these drugs—and, by the way, before the accident I was on one drug just for my heart, I have a pacemaker, that is one of my conditions—the ways that they could help me was by surgery or injection, but I am a hemophiliac and I am also allergic to blood and blood products. So in order for me to go through any kind of surgical procedure, it is a month of pre-treatment, then into the hospital and transfused and then the next day have the surgery or procedure and transfused and then transfused the next day also. I have an unusual hemophilia.

All the allergies and medications are listed. I don't really want to go into all of those unless you want me to. But I did want to go through some of my physical conditions. I do have COPD, chronic obstructive pulminary disease. I am O2-dependent, which I have with me, and I have breathing treatments that are four times a day, plus I carry the little buffer with me too so I can breathe. I never know when it is going to hit, so I am hoping I can get through this without it. The pacemaker I have is a dual pacer, and I have had it now since 1997. I have neuropathy of both my hands and feet that was just recently diagnosed. I have loss of feeling in all these areas. I am not a diabetic, which is where it usually is affiliated. I am not sure why this is happening. I also was just newly diagnosed with osteoporosis, and I am on a very expensive drug for that; the hemophilia, of course; my painful right hip, which is very difficult to treat because of my drug problems. I also have spondylolisthesis. That is in the back where it is breaking down with the osteoporosis, and I am great candidate for fractures. I have a very poor activity tolerance due to the breathing and the difficulty with my walking and so forth since I have had this accident. Now to compound this issue, I also had therapy up until mid-October this—I am sorry, mid-January this year. Sorry about that.

Now, in order to control all these different things that I am suffering with, I have made a list of my medications. I went to Costco, I went to Winn Dixie, and I went to Canada Rx, which is right here in this area. Canada Rx does have some lower prices on some and higher on others or they don't have them. Then they added a shipping charge which negates anything that would be possible. I was told about Costco through Broward County Elderly Services, and I did go there, and they gave me a list of my medications and the prices on them. On their figures, it would be—Costco's figure for a month would be $303.11. At Winn Dixie, it is $406.14, and that is as of this week, depending on whether they are going to go up or not. Okay? My Social Security that I get, less the amount that I have to pay in, the $58, I get $945. I am on disability right now

through work. There was supposed to be long-term disability but because of age and because of what is going on with the Social Security, they will only give it to me for one more year from that. So I will lose that in 1 year, which means everything that we are saying now is even more important. So my total income is $1,882 a month, my fixed outlay is $1,429.40. That leaves me $452.60, if all these figures are correct, to live on and buy my medication. Even at $303, to buy food, clothing, toiletries, paper products, cleaning products, gasoline to get here, anything, it is impossible. I have to make decisions. What do I take? How much of it do I use? And what do I buy first? I have a prescription right here waiting, there is two of them. There is no way. Last few weeks I have had a lot of changes in medication. One of them in particular was this Fosamax. Four pills for 1 month, $63.95 at Costco, and at Winn Dixie, it was $60.19 with AARP as my supplement. Either way that is a lot of money. I could not pay all of my rent this month. Thank goodness they are very kind to me, but kindness doesn't last forever, and I don't know what tomorrow will bring.

I hope I have made this point fairly clear that this is an impossible situation. I have covered myself with insurance. I do have AARP. It is $189 a month—very expensive but very necessary in my case. I think this a problem that everybody needs to hear and know and try to do something about. And before I leave you, I would like to tell you just one little story, if you don't mind.

It is going to be 8 years now in May that my daughter was killed the day before Mother's Day by a hit-and-run drunk driver. She had 3 children, ages 8, 10 and 15 at the time. When she was killed I had the boys for a short year, and I was trying to get them into a more normal situation, and about three or 4 months after her death I took them over to the beach, because their mother did that all the time; they loved the beach. And the 8-year-old was just sort of playing with the seaweed, and the 10-year-old at that time—he is now 18—the 10-year-old asked me, he says, "Grandma, did my mother really make a difference in this world," and I said, "Of course she did. She made me a mother. She was my daughter, and I could love her, made your uncle to have a sibling, and without her I wouldn't have the three of you to love and watch grow up." And he says, "Well, grandma, did you ever stop to think that if I threw this little pebble in the ocean, that that ocean and any ocean it touches would never be the same again?" And I said, "How astute of you, how smart you are. No, I never did." He says, "Okay." He says, "My mother did make a difference." I said, "She certainly did. She brightened everybody's life that she came near." He says, "Okay," and he took it and he skipped it across the ocean surface. That is for my mother who made a difference. This little 10-year-old boy made a great difference in my life, and now I am this bolder and I am going into the ocean and I want you all to make a change. Thank you.

[The prepared statement of Resi Coplan follows:]

PREPARED STATEMENT OF RESI COPLAN

On January 15, 2002, I was run off the road on 595 east bound by a car that was coming into my lane making it necessary for me to go onto the emergency lane and, with the car still coming at me , I then went into the wall. My car almost turned over as it rocked back and forth finding it's way to part grassy median and shoulder.

My defensive driving was affective, since I was not hit by the uncontrolled car. Had I been, it would have turned my car right into two lanes of morning traffic and I don't like to think of what the results might have been.

This left me with an injury that exacerbated the condition in my lower back. This forced me to take sick time and vacation pay until it was depleted. Then I was put on long term disability (which is only good for a 2 year period do to my age and social security status) supplied by my place of employment. This disability will end on April 18th, 2004. Since that time, I have not been able to return to work and my health has been going downhill from there with several other problems.

During my recovery period, I was told to take Neurontin 300mg. to control the severe pain I was in. This was much to strong for me and I asked the doctor to give me a much lower dose which he did (100mg 3 to 4 times a day). One capsule kept me out of commission for 24hours. The doctor insisted I increase the dosage in order for it to be therapeutic. I did increase the dose to 300 mg. the evening of July 6th, 2002. I was so anesthatized, I didn't know exactly where I was and thought I was in the middle of my bed when in fact, I was on the edge of my bed and thew myself out on my head while my feet did a backward summersalt and I broke my left foot. Now I have to nurse my right hip and left fractured foot. I was in the hospital from July 7th, 2002 until August 20th, 2002. On discharge I had to have live-in nursing care until mid October, 2002. After tht I have been on my own and just trying to survive through the pain and disability ALONE.

There are treatments available for this back condition, but I am not a good candidate for any of them due to the following conditions: 1. Factor Eleven Deficiency (a bleeding disorder). 2. I am allergic to blood products. I would need multiple units of Fresh Frozen Plasma for any procedure that would cause any trauma to my body and cause bleeding or the potential of that happening. 3. Pacemaker (dual) since 1997. 4. COPD and oxygen dependent with breathing treatments four times a day. 5. Very poor activity tolerance due to breathing problem and severe pain in right hip and lower back that has become much worse since the accident. 6. I am allergic to a large list of medications or they are contraindicated due to the bleeding disorder. They are as follows: A. penicillin; B. amicar; C. sulfa; D. novacaine; E. benadryl; F. cipro; G. horse serum; H. cat gut; I. Blood products; J. No asiprin or asiprin like products like antiinflammatory drugs that thin the blood.

My medication bills alone have have been over $3,500 last year.

Then comes the other necessary expenses such as: A. Rent $ 625.00/mo; B. Electric, 80.00/mo on average for the year; C. Phone, 59.00/mo; D. AARP, 189.00/mo for medicare supplement in addition to medicare part A & B; E. Cancer/hospital 86.40 for additional insurance protection; F. Cable, 58.00/mo (my only entertainment); G. Long term ins.; H. Home health and Nursing home care 267.00/mo; I. Auto insurance, 68.00/mo.

This amount of routine monthly expense comes to $1432.40 per month that must go out each and every month. This does not include any medication expense or over-the-counter drugs that are needed such as stool softeners when taking medications that cause constipation and can lead to bleeding which, in my case would be a stay in the hospital if it was left untreated. I also need tylenol for pain and/or headache due to some of the side effects from the drugs.

My total income for the next year (till April 18th 2004) is $1882.00 = social security and disability benefits combined -1432.40 = bare basic outlay $ 449.60 This is what is left before I can think of medication, much less food, gas, or any other expense, i.e., soap, shampoo, cleaning supplies.

I have an oxygen concentrator the takes electricity to run. When I call FP & L, they told me that it will cost me approx. $50.00/mo to run as the doctors have ordered. Well, now what do I do. I JUST DON'T USE IT UNTIL I CAN NO LONGER GET AWAY WITHOUT IT.

As for my medications, I have either stopped taking them or have cut the dosage down in half and that is only if I MUST TAKE THEM.

IF YOU TAKE $449.60 and multiple that by 12 months you get $5395.20. Now look at the medications $ 3500.00/yr and divide by 12 months equals $291.66.

$449.60 -291.66 = meds

Total left for the month is $157.94. for all other expenses including any new Rx that the doctors think a what I need. This leaves $36.44/wk. to save for emergencies, any co payments . . . just everything else.

I cannot imagine that one year from now I will only have $945.00/mo to continue with my life and "survive?"

I submit these information respectfully,

Mr. GREENWOOD. Thank you. That was—I can't imagine it being more beautifully said. And you will make a difference, and you have already. Thank you.

Mr. Sweed.

TESTIMONY OF GENE SWEED

Mr. SWEED. Congressman Greenwood, Congressman Deutsch, my name is Gene Sweed. I am 67.5 years old, and this is what happened to me in only 2.5 years of Medicare.

In the year 2000, upon turning 65, I selected an HMO, Avmed, as my provider. The first year they allowed me $3,000 per quarter in prescription allowance with an average deductible of $10 to $20. This was more than enough to take care of my needs, and I felt we were secure. After my annual exam, it was determined I had a lot of things wrong with me, such diabetes, high blood pressure, an irregular heart beat, prostate cancer and arthritis, among others that are too numerous to mention.

The HMO allowance still was sufficient for us to live the lifestyle we chose. Season tickets to hockey, 42 games, the ability to go to dinner before every game, going to the theater often and going out with our friends as often as possible. In years 2001 to 2002, the allowance dropped considerably to $1,250 a quarter. We felt that by tightening our belts we still could be close to our budget. So first we gave up the theater, we changed our Hockey to 13 games and of course the eating out dropped. And fortunately for us, Walgreen's was able to provide generics for most of the prescriptions to help keep the cost down. I also started to skip my medicine occasionally so I would not go over the allowance. See, the problem is when you are an HMO you have your allowance, but you don't know what they are charging the HMO with Walgreen's and them, so you don't know where you are into your allowance. And it is scary because you pay everything over that. We learned at one time I had one prescription that was a new item, and my co-pay was $80. So I can imagine what the heck they had to charge to the HMO.

Now, for the year 2003, the allowance was dropped considerably to $250 a quarter. Two hundred and fifty dollars a quarter was not going to cut it. This is not acceptable with me, so I switched to Foundation, which has now become Vista. The main reason I did that again was to try to stay with the same doctors. Fortunately, they had the same doctors, so with $250 a month I am okay, and I have the same doctors again; I don't have to start all over again.

We are in the process of adjusting again, though. We do not eat out again like we did before. If we do eat out, we make sure that we take home a doggy bag. I used to laugh at people for doing this, but we take home a doggy bag. If somebody is offering to show their product and is feeding us, we always go, even when we are not interested. Meals at home have changed to items that you can make more meals out of, such as soup, spaghetti, meatloaf, et cetera, and portions are getting smaller. I also have skipped taking my medication more frequently. Now, my wife doesn't say anything, but she is trying to keep me alive, and this is her goal by doing this, by doing that. She is an excellent budget manager. Now, I have also started to skip taking my medicine more frequently.

The biggest concern for me is that if my wife should precede me how I would survive as it does take my wife's money management skills to make it work. But one thing I don't understand is if the manufacturers complain about their costs, why are they running commercials on TV for prescription medication when it is expensive to produce them and air time is very costly, especially on the main channels. You only get the prescription from your doctor. They take their samples in, they give them to the doctor, if they talk to the doctor, sometimes they even talk to just the office manager and they don't go into everything like what the side effects are. And, again, sometimes the side effects cause you to take another prescription. They may affect your stomach, they may affect something else. And that is a problem that we don't understand. So I thank you very much for your time, and if you have any questions, I would gladly answer them.

[The prepared statement of Gene Sweed follows:]

PREPARED STATEMENT OF GENE SWEED

My name is Eugene (Gene) Sweed I'm 67½ years old and this what has happened in only 2½ years on medicare.

In the year 2000 upon turning 65 I selected Avmed as my H.M.O. provider. The first year they allowed me $3000 per quarter in prescription allowance with an average deductible of $10.00 to $20.00 this was more tan enough to take care of my needs. After my annual exam it was determined I had a lot of things wrong with me, such Diabetes, High blood pressure, an Ireggular Heart beat, Prostate Cancer and others to numerous to mention.

The H.M.O. allowance was sufficient for us to live the lifestyle we chose. Season tickets (42 games), The ability to go to dinner before every game. Going to the theater often,and going out with our friends quite often.

In years 2001 & 2002 the allowance dropped considerably, to $1,250 per quarter. We felt by tightening our belt we would be close to our budget. First we gave up the Theater, changed our Hockey to 13 games and of course our eating out dropped. Fortunately Walgreens was able to provide generics for most of the prescriptions and keep the cost down. I also skipped taking my medication occasionally so I would not go over the allowed amount.

One problem is we do not know what the charges are only the deductible. For the year 2003 the allowance was to be approximately $250.00 per quarter. This not being acceptable me I switched Foundation now Vista at $250.00 per month. We are in the process of adjusting again. We do not eat out before every game. If we do eat out we are making sure we have a doggy bag to take home, When a company offers to show their product and are feeding us we always go even when we are not interested. meals at home have changed to items that you can many meals out of such as soup, spaghetti, meat loaf etc. with portions getting smaller. I also have skipped taking my medication more frequently. The biggest concern is if my wife should precede me is how I will survive as it takes my wife's money management skills to make it work. One thing I don't understand if the manufacturers complain about their costs why are they running commercials on T.V. when it expensive to produce them and air time is very costly? We can only get a prescription from our Dr. so it is his/her choice.

Mr. GREENWOOD. We thank you, Mr. Sweed. Thank you, all of the panelists, for coming. And the Chair is going to recognize himself for about 10 minutes for questions. Since there are—we don't have the full committee here we can be a little bit looser with time than we usually are in Washington, which is nice.

Let me start with you, Ms. Coplan. Could you—I don't know that I heard in your testimony that—where were you working before you had your accident? What was your employment? Maybe you could tell us a little bit about your employment history over the years.

Ms. COPLAN. Certainly. I became a nurse in 1971. I have been nursing all during that entire period. My general background was ICU, emergency room, labor/delivery, newborn nurseries, recovery, the heavy areas.

Mr. GREENWOOD. Employed by whom during this?

Ms. COPLAN. Different hospitals. I had also gone into California and Washington to get some varied experiences there. Their medicine is a little different sometimes in certain areas. And I had family there as well, so it was a dual purpose. But the last 13 years I worked for Bell Quality as a instructor for home health students.

Mr. GREENWOOD. And did Bell Quality provide you with a prescription drug benefit when you were employed there?

Ms. COPLAN. I had—at the time, I had United Health Care, which you had a co-payment, and at the time that I got it it was like $5 or $15, depending on——

Mr. GREENWOOD. Per script.

Ms. COPLAN. Depending on whether it was generic or brand. And then it went up and it continued to go up. And then I became eligible for Medicare Part A with United Health Care as backup.

Mr. GREENWOOD. And United Health Care, was that——

Ms. COPLAN. My employer paid that for me.

Mr. GREENWOOD. Okay.

Ms. COPLAN. Okay. So it wasn't a bad deal, and I was working, and there was money coming in. And when I had the accident, of course I couldn't afford the United Health Care at that time.

Mr. GREENWOOD. And how much was that?

Ms. COPLAN. I don't know. I know it would have been a COBRA payment, and it would be close to $400 a month, I think it was. And of course that was out of the question, so I went to Medicare Part B.

Mr. GREENWOOD. And that was a full health care plan. That was not——

Ms. COPLAN. Yes.

Mr. GREENWOOD. [continuing] just prescription, that was a full health care plan.

Ms. COPLAN. Yes.

Mr. GREENWOOD. Okay.

Ms. COPLAN. It was not a bad plan. But then I went to Medicare Part B and in the interim also took AARP because I was scared. I needed the supplement.

Mr. GREENWOOD. And what does—what you purchased from AARP is that what we call a Medigap plan?

Ms. COPLAN. Yes. Yes, at $189 a month. And I am waiting—I have been notified that they are going to go up in premium, which is going to knock me out.

Mr. GREENWOOD. Okay. And that would pay your co-pays and your deductibles.

Ms. COPLAN. It has a varying deductible. One drug, one of the most expensive ones of the four pills, there was a dollar off on that one with AARP. Okay. It wasn't sufficient enough to even warrant. And yet there would be another one where they would pay half. So I don't understand why the drug companies have this big gap so that AARP can't be more efficient.

Mr. GREENWOOD. And when you left—because of your injury, when you left Bell Quality they did not provide you with any continual—there is no prescription drug benefit unless you buy the entire United Health Care COBRA policy; is that right?

Ms. COPLAN. No. I am still considered an employee there until April when my disability ends next year, April 18, to be exact, 2004.

Mr. GREENWOOD. You are going to really be in the sauce then, aren't you?

Ms. COPLAN. I am going to be under a bridge somewhere with my oxygen and my breathing treatments and—I will be homeless, yes.

Mr. GREENWOOD. Let us hope that doesn't happen. Mr. Sweed——

Mr. SWEED. Yes, sir.

Mr. GREENWOOD. [continuing] tell us a little bit about your employment past, if you would.

Mr. SWEED. Okay. I had worked for a company that sold plating metals, had no coverage at all. It was just the owner and myself. He was in his seventies. I did call around to try to get some sort of insurance, and they were asking figures like close to $300 a month just for the premium, so I couldn't——

Mr. GREENWOOD. How long had that been your employment?

Mr. SWEED. When I came here to the Miami area in 1996 until I retired at age 65, which was 2.5 years ago.

Mr. GREENWOOD. Okay. So you had no health insurance whatsoever all that time?

Mr. SWEED. No, sir.

Mr. GREENWOOD. You just paid everything out of pocket.

Mr. SWEED. Right. Well, we weren't sure that of what was wrong, because I wasn't even going to the doctor. So we had no concept of what was going on. Now I am at a point that I take 14 pills a day and then 3 on an as-need basis that counteract some of the things that the other pills do.

Mr. GREENWOOD. Have either of you, Ms. Coplan and Mr. Sweed, ever tried to find out whether some of the plans that are offered by the drug companies themselves, like Together Rx, would benefit you? Have you ever had any contact with—a number of the pharmaceutical companies provide discounts or in some cases even free medications to people who are struggling. You are nodding your head, Ms. Coplan. What has been your experience?

Ms. COPLAN. Yes, I have checked into it. I have had doctors give me these pamphlets that they have left, and I have also been on the Internet looking around. Some are beneficial and some are not. I would need a secretary to keep track of where I would send what drug for the best benefit. And it takes some doing to keep that record. I think it is—there has got to be something else. There has got to be some way of controlling it.

I want to ask you a—may I ask you a question?

Mr. GREENWOOD. Absolutely.

Ms. COPLAN. Thank you. You know when people were smoking cigarettes and they raised the taxes to help defray the cost of the medicines and so forth and the medical care the patients needed that were addicts. Why can't they do the same thing? I was at a

store the other day waiting for a friend of mine while they grocery shopped for me, because I don't do that anymore. And I was sitting in the car, and one out of every four people came out with one, two, three big packs of beer, wine. Why can't they just tax them as well to help us seniors. There are bottles of liquor that cost over $100. Five dollar taxes would sure help out a senior, and it won't hurt them, but it would benefit us.

Mr. GREENWOOD. We will take that into consideration. I am sure that the State of Florida probably does impose taxes on its spirits, and the Federal Government has taxes, and I am sure all of the beer and wine lobbyists will be rushing to help us get that passed.

Ms. COPLAN. It was a thought.

Mr. GREENWOOD. Let me—you, Mr. Sweed, have you contacted any of these programs that are offered by the pharmaceutical companies?

Mr. SWEED. Until very recently I hadn't even been aware of it, but just hearing what Ms. Coplan said, needing a secretary would probably discourage my wife because she does most of that for me, not wanting to run here and there and everything else. Having the convenience of Walgreen's right out the back door is a big difference for her.

Mr. GREENWOOD. Right. Well, you might want to look into it. I can't guarantee you that it won't be hassle-free or without its complications, but I would certainly hope that that would be a preference before you—things got so dire that you were actually homeless, as you predicted.

Ms. COPLAN. Unless I can go back to work, which I doubt. I mean you are seeing me at my best today for some reason. I am not usually like this. I usually have a much more difficult time breathing.

But getting back to those different plans, if you don't categorize all these different ones and know what your medications are, some plans have your medications, some do not. Some will give you a nice discount, some won't. What I have become is a beggar. "Doctor, please, do you have samples. I can't afford my medicine." I have two prescriptions right here that I am holding onto because I had to go to the drug store the other day to get over-the-counter medicines that cost me—sorry, they had to give me a refund because they charged me too much—$21.98 for the month.

Mr. GREENWOOD. And what is the prescription for?

Ms. COPLAN. It is not—this is not a prescription, this is just over the counter.

Mr. GREENWOOD. Oh, I see.

Ms. COPLAN. Because the medications they give you are very constipating, and if I don't do something about that, I will bleed, and then I end up in the hospital. Costs them a whole lot more. So this simple little thing is a big cost to me that nobody takes care of. But the prescriptions that I have, because I cannot take pain medication, I am not sleeping. It is very difficult for me to get comfortable. The pain is terribly exaggerated at night because I guess it is the end of the day. And I take Zanex. Well, Zanex is not that expensive, but they put me on a new drug called Ultran which helps and it is very expensive. So which one would I get?

Mr. GREENWOOD. Mr. Sweed, I understand that you have made some attempt to get pharmaceuticals from Canada?

Mr. SWEED. We had talked about it, my wife and I, and the Internet. In fact, very recently, we have a friend of ours that her son had gone through the Internet, had mixed medicines and at 30 some odd years of age passed away, and we backed away from it real fast when we saw that happen, because we were concerned. But we had talked about it and had not acted on it yet.

Mr. GREENWOOD. Let me ask you both, Ms. Coplan and Mr. Sweed, a question. If the Congress passed a prescription drug plan that had roughly qualities such as I am about to describe, you had a $250 deductible so that the first $250 was right out of your pocket and you would probably both spend that in the first month, and then if Congress paid roughly half of the cost of your prescriptions up to some point, let us say $3,000—these are rough figures—$3,000, and then you were on your own for a while, but if it ever got up to around $6,000, that then everything would be covered by the Federal Government, does that sound roughly like that would be a significant help to you? I am looking at your figure of—I think you said that if you went to Costco, your drugs would cost about $300 a month.

Ms. COPLAN. Three hundred and three.

Mr. GREENWOOD. Right.

Ms. COPLAN. That was just the latest figure, and that was last week.

Mr. GREENWOOD. Right. So if you used that—if let us say your deductible was spent in the first month, if a plan could cover half of your prescriptions——

Ms. COPLAN. It would be a big help.

Mr. GREENWOOD. [continuing] it would be a big help, at least for a good portion——

Ms. COPLAN. I could go buy bread.

Mr. GREENWOOD. You could go buy bread.

Ms. COPLAN. Yes.

Mr. GREENWOOD. Now, let us not get extravagant here.

Mr. SWEED. I am looking, my wife has made a sheet for me of what the co-pays have been. Not counting some of the special ones that I have had, like for the arthritis I had a shot in my knee that cost me $175 by itself, but that is a rare thing, overall, I am running about $250 to $260 a month just on deductibles.

Mr. GREENWOOD. What is your monthly income? Do you have anything besides Social Security?

Mr. SWEED. I have my Social Security, that is it.

Mr. GREENWOOD. And how much is that, if I may ask?

Mr. SWEED. Net after Medicare comes out is about $720, I think it is.

Mr. GREENWOOD. Okay. Final question. Mr. Lipscomb, let me turn to you. Could you describe for us what AARP generally offers seniors in Florida through the various plans that you have available?

Mr. LIPSCOMB. We offer prescription drug coverage. Not coverage in the sense of insurance but to have the ability for group buying, so to speak, through one of our providers. AARP doesn't do any of these things per se itself, but what we do is we vet providers and make sure that what they are doing is in no way taking advantage of the people.

Mr. GREENWOOD. When Ms. Coplan says that she has AARP, I assume——

Mr. LIPSCOMB. That is what she is talking about.

Mr. GREENWOOD. [continuing] she means—well, I am a little confused now, because I asked her if she meant a Medigap policy. Is that what she has?

Mr. LIPSCOMB. She has both, unless I am mistaken, based on her description.

Mr. GREENWOOD. I am sorry, she has what?

Mr. LIPSCOMB. She has both——

Ms. COPLAN. Yes, I do.

Mr. LIPSCOMB. [continuing] types of——

Mr. GREENWOOD. So she buys a Medigap policy.

Mr. LIPSCOMB. Right.

Mr. GREENWOOD. And that costs her $189 a month. That does or does not provide prescriptions?

Ms. COPLAN. The entire package is a discount on my drugs.

Mr. GREENWOOD. One hundred and eighty-nine dollars.

Ms. COPLAN. And the Medigap, if you want to call it that, where they take up the 20 percent that Medicare doesn't——

Mr. LIPSCOMB. Right.

Mr. GREENWOOD. Right. So you get the Medigap plus you get some prescription drug discount.

Ms. COPLAN. Discount we call it, I think.

Mr. LIPSCOMB. And that is under United Health Care, which is who she was talking about a while ago. In other words, that is who our licensed provider is, United Health Care.

Mr. GREENWOOD. I see. And have you been able to figure out what that discount is worth to you a month? I know you said it varies from half in some drugs to a dollar in other drugs.

Mr. LIPSCOMB. It is going to vary radically, Mr. Chairman, depending on the particular prescription.

Ms. COPLAN. It does. I really does, because when I just got one of the prescriptions done through AARP at Winn Dixie there was a dollar discount. But on another drug at Winn Dixie, it was half that AARP picked up. So there is not consistency, which is what? And they were both generic.

Mr. GREENWOOD. Mr. Lipscomb, when you buy these policies, $189 a month, do you have any rough calculus as to how much of that would be helping her with the prescription side of the ledger?

Mr. LIPSCOMB. I really don't, Mr. Chairman. I can inquire for you.

Mr. GREENWOOD. Would you do that?

Mr. LIPSCOMB. I would be glad to.

Mr. GREENWOOD. Would you provide that information to the committee?

Mr. LIPSCOMB. Yes.

Mr. GREENWOOD. Thank you.

The Chair recognizes the gentleman from Florida.

Mr. DEUTSCH. Thank you, Mr. Chairman. Mr. Lipscomb, does AARP have a position—you mentioned the position about the Internet pharmacies, but specifically about the walk-in entities that have shipped drugs to consumers—actually, I guess Ms. Coplan mentioned she had gone to the Canadian drug stores phenomenon

that have been established in south Florida, I don't know—throughout the country at this point?

Mr. LIPSCOMB. Congressman Deutsch, we have not taken a position saying that these people should be closed down or anything like that, because we don't have anything to offer these people in lieu of that option. What we have said to people is you should be very cautious in terms of making sure you understand who you are buying from and that these are of the quality that you anticipate that you are getting. And that is a very difficult thing to determine for people like our two witnesses here. I mean it is difficult for the Department of Health to determine sometimes, much less for a private citizen.

Mr. DEUTSCH. This is sort of a follow-up to one of the things the chairman was mentioning, but in the next panel we will have—several witnesses will talk about a variety of programs that exist for seniors to access more affordable medicines. They include the Orange Card by Glaxo, Eli Lilly's Answer Card Program to the Together Drug Program. Have you heard of any of these prior to this hearing, either one of you?

Mr. SWEED. The only one that I have heard from is because I am a diabetic, Accu-Chek stays in constant touch with me. They have even sent me a free monitor, they have given me a choice, they will make sure that the strips are free when I go to the drug store, et cetera. But they are the only one out of anybody that has made any contact and has done anything with me.

Mr. DEUTSCH. And, Ms. Coplan?

Ms. COPLAN. No, I haven't had that. The only thing that I would like to comment on right now is the fact that my breathing treatment takes two different types of medication. There was one that I was on. It was Zoponex that did not make my heart race when I used it in a breathing machine.

Mr. DEUTSCH. Right.

Ms. COPLAN. This drug right here, six of these boxes with four in it, four treatments, one a day, costs $56 every 6 days. What I had to do was go to the lesser one. This one is longer acting and has a lot less side effects for me with my heart condition. But I had to go back to the one that had tremendous side effects because I could get it for free through Medicare. Medicare will pay for it. So I have to now use less medication because of the side effect, because I can't afford this one.

Mr. DEUTSCH. Ms. Coplan, let me—again, I appreciate you being so forthright with us, and it really has been really very helpful, and I think, as you mentioned, your analogy of the boulder and the ocean I believe is really accurate. But, again, just to try to really have an understanding on somewhat of a personal basis what you are going through, have you explored Medicare Plus Choice options in terms of—have you looked at that, HMO options for yourself at this point?

Ms. COPLAN. Having been a nurse, having dealt with HMOs for patients, having had four of my friends on HMOs that are crying, they tell me what is going on, if it wasn't for my two doctors, I wouldn't be sitting here today, I would have been dead. They saved me, pulled me through it. They are not HMO doctors. My friends who have been on HMOs and Foundation, or whatever you want

to call them, are being every few months different doctors; doctors don't know them. If a doctor walks in and tries to treat me that has never seen me before, there is a danger there. Thank goodness I have a medical background. Otherwise they can do damage.

I had 14 doctors in the hospital when I was there. Those 14 doctors were making prescriptions all over the place—give her this, do this, do this—and no one was watching the other. I was the chief, and I made them the Indians. And I took my own case and I took a PDR and I started going through the medications, because I was very sick and I said something is making me ill. And I stopped all my medication and I said, "You are not going to give me anything more. You speak to this doctor and me and clear it through them before you order anything." And I had to take that initiative with the help of my doctor at my side to confer with in order not to be overdosed or drugged differently. If I go to an HMO and I have to go see a doctor who doesn't know me, I am facing the same monster again. And I would rather be without medical treatment.

Mr. DEUTSCH. Let me go back, and, again, you seem like you have been a very aggressive consumer. I mean you mentioned Costco, Winn Dixie, Canada Drug.

Ms. COPLAN. And the Internet.

Mr. DEUTSCH. And the Internet. First off, do you have—and this, Mr. Sweed as well—I mean do you have personal friends that are purchasing drugs through the Internet at this point in time? I mean do you have friends who——

Ms. COPLAN. I have had some that have talked to me that they might do so, and I told them I didn't think it was a wise decision, because you didn't know what bathtub it was made in. That was my feeling. I would rather go to somewhere were I understand the pharmaceutical company by reputation. So before I was ever even here, and I am glad to hear you confer that this is not a good idea to go just to anyone——

Mr. DEUTSCH. Let me be really clear what I said. I think there is this—the phenomenon is that I think we are trying to address this issue. It is not a good idea in the sense that there really is no oversight.

Ms. COPLAN. Okay.

Mr. DEUTSCH. And there have been some anecdotal stories of problems. I think for some people they are making a personal choice if they feel there is no choice. I mean given the choice between if there really is no choice, if there is no government program—I mean you might, once your disability ends, be eligible for Medicaid. I mean at $1,800 a month you are probably not eligible for Medicaid.

Ms. COPLAN. No, I am not.

Mr. DEUTSCH. But at $900 you very well might be with certain of the issues involved. And that is why I am not familiar with the—you mentioned you had gone to Broward County Social Services in terms of medically needy issues, and basically you found nothing available in any kind of medically needy programs in terms of county government or State government at all.

Ms. COPLAN. The only thing that they said to me was that Costco is now allowing anyone, even without a Costco card, to go into their pharmacy and use it. And it was supposed to be a huge discount,

it was something that had just been introduced within the last 2 weeks.

Mr. DEUTSCH. And Broward County——

Ms. COPLAN. That is when I went to check—I am sorry.

Mr. DEUTSCH. So you physically went to Costco or you called or you——

Ms. COPLAN. I went there myself with my list and they gave me their prices.

Mr. DEUTSCH. So the next time you purchase to fill prescriptions you are going to fill them at Costco at this point? Is that your expectation?

Ms. COPLAN. I am not clear on one point yet; I haven't been able to clear that up. Whether AARP discount would be good at Costco like it is at Winn Dixie because I may be better off with some of the drugs going to Winn Dixie or to other one of the pharmacies that I am allowed to go to for the discount that I get with AARP on some of the drugs. But, again, here is the Secretary. And how much gasoline can I afford to buy at $2 a gallon?

Mr. DEUTSCH. Right. When you checked on the Internet in terms of prices, were the Internet pharmacies offering prices that were less than you had seen at Winn Dixie or Costco—not the walking pharmacy you mentioned, not the counter drug pharmacy locally, but the actual Internet pharmacies?

Ms. COPLAN. There were some that seemed okay but it wasn't enough of—I didn't get enough of an interest in doing it that way and waiting the 2 weeks. I would rather go to Winn Dixie and have my medication now, because you go to the doctor and they give you a month's supply. You have got to go back to the doctor and get another month's supply. So my overlap would not be there, I would need the drugs on a continuous basis. So my thought was I will go to Winn Dixie or I will go to Wal-Mart, wherever it is.

Mr. DEUTSCH. Mr. Sweed, you were mentioning—I saw you nodding when I was asking the question about friends who are using Internet pharmacies at this point?

Mr. SWEED. We have some friends that I am not sure whether they are using the Internet or not but they are always waiting in the mail for something to come. And, again, they have a problem because in the mail they can't control when it gets there; sometimes it is late or whatever. See, my situation is different than theirs too, because in my case not every pharmacy will handle HMOs, so there is a pharmacy in our area who is a very big discount pharmacy but won't touch an HMO. They said by the time they get paid and what they allow them to make and all it is not worth it to them, it is cost prohibitive. So I am at a little bit of a disadvantage in that I don't have much of a choice other than what I have here.

Mr. DEUTSCH. So you had mentioned your prescription drug copays now is about $250, $300 a month that you are paying?

Mr. SWEED. Right. This year with Vista is $250 a month is what I am allowed. Now, I just started as of the 1st of the year so I don't know whether I have gone over yet or not. If I have, then they will send me a bill. Again, like she said, I try to——

Mr. DEUTSCH. So you switched to Vista HMO. You left Avmed.

Mr. SWEED. Right, because Avmed only wanted to give me $250 a quarter.

Mr. DEUTSCH. Two-fifty a quarter. Okay.

Mr. SWEED. Right.

Mr. DEUTSCH. And the physicians that you go to were members of both Avmed and Vista?

Mr. SWEED. Right. That is exactly why I stayed with Vista—went with Vista, I am sorry.

Mr. DEUTSCH. Okay. So Vista, at this point, is $250 a month of coverage.

Mr. SWEED. Right.

Mr. DEUTSCH. And you are only into, what, your second month of Vista at this point?

Mr. SWEED. Yes, sir. As of the 1st of the year.

Mr. DEUTSCH. So you really don't know——

Mr. SWEED. Right.

Mr. DEUTSCH. [continuing] this sort of black box thing, if you are going to get a bill at the end of month or end of the quarter for additional coverage.

Mr. SWEED. And the problem you run into, like Ms. Coplan said, is side effects with things that help the arthritis. The arthritis is the biggest problem. Okay? That is why I am in a chair, the legs can't handle anything.

Mr. DEUTSCH. Right.

Mr. SWEED. And Celebrex is one of the few things that really works, but Celebrex can hurt your live, can hurt your kidneys. So, therefore, I can't take it all the time. I am taking over the counter, we will say, not Exedrin, Tylenol or something like that. So you are playing a game that way to try to kill the pain. I mean I have had pain most of my life because I played football, this came early and it has been getting progressively worse. I have lived in pain, that doesn't bother me, but as it gets worse it gets tougher. Like she said, going to sleep at night, if I don't take something, I don't sleep. I must take something that is going to put me under or relax my system so much and help kill the pain.

Mr. DEUTSCH. Mr. Lipscomb, did you want to sort of elaborate on anything?

Mr. LIPSCOMB. I was going to say, Congressman Deutsch, that 2 years ago we went to the Florida legislature and got them to pass legislation which would allow anybody on Medicare to buy prescription drugs at 9 percent above the average wholesale cost. We have never been able to put that program into operation because we can't establish what the average wholesale cost is. So when you are asking the two witnesses about numbers in terms of drug costs, it is a moving target, as I am sure both of them can tell you, because they are going to the pharmacy 1 day and it cost one thing, and then with no apparent reason it changes, and that is why it is very difficult for Mr. Sweed to know where he is in terms of this, because the prices fluctuate up and down and nobody tells them what is going on. So disclosure would even help in some cases so that people know what they are dealing with in terms of HMOs or in terms of insurance programs or what have you.

Mr. DEUTSCH. Mr. Sweed, if you can just elaborate just so I understand this. The $250, because, again, especially from Mr.

Lipscomb's follow-up, you literally have no idea where you are in the month in terms of the——

Mr. SWEED. I have no idea.

Mr. DEUTSCH. And there is no way to figure it out.

Mr. SWEED. All they do is when I get my prescription it comes on there whether it was a $10, a $20——

Mr. DEUTSCH. Just the deductible.

Mr. SWEED. [continuing] deductible, my co-pay. That is all I know.

Mr. DEUTSCH. You don't know the price.

Mr. SWEED. I have no idea.

Mr. DEUTSCH. If you ask them, would they tell you?

Mr. SWEED. I would guess if they knew; yes, possibly. It depends on, again, whether it is the clerk or the pharmacist. They may know.

Mr. LIPSCOMB. Many times the technician or the pharmacist will say, "Until we run this through the computer and see which programs we are dealing with, we don't have any idea what it cost."

Mr. DEUTSCH. I mean the reality is it could not even be a large discount. I mean it could be a way that they are just manipulating that the $250 is really not $250.

Mr. LIPSCOMB. Exactly.

Mr. DEUTSCH. It could be $100, it could be—I mean it is just an adjustment, it is just——

Mr. LIPSCOMB. One of the things that AARP has tried to do with our members, because our members are very responsible people, so we suggested to them, as these two witnesses have said to you, to ask your physician to prescribe generic drugs when it is possible, because it costs Medicare less, it costs the health care system less. Then we sat down and had a graduate student call pharmacies to check on the cost of generic drugs. The difference between the average wholesale cost on some generics goes into the thousands of percent markup, and it is just all over the map. And so even though these folks are trying their best to do it as economically as possible——

Mr. DEUTSCH. Yes. Let me just mention, I mean I am sitting here thinking to myself these are two 67-year-olds. This is not—the reality is this is not typical seniors. You are much more able to do this than the 77-year-old, the 87-year-old, for that matter, the 97-year-old, because the reality is the 97-year-old who doesn't have someone to help them or the 87-year-old in south Florida is not doing what either one of you did.

Mr. LIPSCOMB. But even the——

Mr. DEUTSCH. No, but you know what I am saying? So I think we are seeing in terms of—I mean we are seeing young Medicare beneficiaries, very capable Medicare beneficiaries who are just totally stymied. I mean the two of you—and, again, I am just saying this from my perception—you are about as competent Medicare beneficiaries, and he is shaking his head, and this is probably the expert in Florida of seniors, so he knows what I am talking about, that you two are about the epitome of well-informed, aggressive, good consumers, and you are basically stymied. I mean so, you know, the 87-year-old is not going on the Internet, most likely is not going on the Internet and is not doing the kind of aggressive

shopping and price comparison that you folks are doing. Go ahead, I am sorry.

Ms. COPLAN. May I ask you something? I happen to have brought my Winn Dixie pharmacy slips with me, and with AARP, on one drug, I saved $20.01; on the other drug I saved $1. It tells me that the one I saved $1 on was $62.95, so add the dollar it was $63. But the other one I paid $10.08 for, and I saved $20.01. Big gap, big difference.

Mr. DEUTSCH. Thank you all very, very much, and I appreciate it. I am sure we will do some follow-up as well. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman from Florida. We have been joined by a colleague of ours from New York, Congressman Eliot Engel, who I will tell you has an ulterior for coming down to this hearing. His mother lives in Congressman Deustch's district, and he came down and got to visit his mother and do the hearing, and lobby his mother to vote for Congressman Deutsch all at the same time. The gentleman from New York is recognized for 10 minutes.

Mr. ENGEL. Thank you. I thank the chairman, and it is good to be here, and I questioned my good friend, Congressman Deutsch, when my mother told me she got the notice in the mail about this hearing I serve on this committee, so I wanted to know why I didn't know anything about it. But we all—and I appreciate being here with my two colleagues who I want to tell you have really been at the forefront of fighting for affordable prescription drugs. One of the things that we try—and I am not on the Oversight Subcommittee of the Commerce Committee, but I am on the Health Care Subcommittee, and we have, like everyone else, been grappling with the whole issue of affordable drugs.

You know, when I was first elected to Congress 14, almost 15 years ago, and my mother has been a resident of south Florida for 25 years, I said to her, "What is the thing that we can do, and this is back in 1988, most to help senior citizens?" And she said to me back in 1988, I will never forget it, "To get us some help with prescription drugs." She is a Medicare—obviously a person on Medicare and tells me all these stories about seniors who cannot afford to buy food and have medication and have to compromise, and that is not something that should be.

Mr. Lipscomb, I am wondering if—because I am interested in AARP's position on some of these core issues. The whole quality of care issues are created by the walk-in pharmacies that we have or by ordering drugs on the Internet. They obviously can potentially increase the risk for drug interactions. Tell me a little bit, and if you have done it already, I apologize, what the AARP believes that these practices do to Doctor/patient relationships or pharmacist/patient relationships. I mean one of the things that I think is disgraceful is that we in Washington haven't really gotten hold of this whole issue. There is something so terribly wrong when seniors have to go to the Internet or have to find other ways of getting drugs that they can afford, because the drugs that they are talking about cannot afford. So I am just wondering if you could just enlighten us about AARP's position because of the potentiality of drug interactions.

Mr. LIPSCOMB. Thank you, Congressman Engel. Clearly, we do feel that it is detrimental to the doctor/patient relationship. You heard Mr. Sweed and Ms. Coplan both describe how crucial it was that their doctor have an understanding of the interaction of the particular pharmaceuticals that they were taking. And in Ms. Coplan's case, she said she felt like she would be at risk if they prescribe the wrong drugs. So if she is going to a computer to get her drugs, then that piece is going to be missing. So we are—we seriously caution our members in terms of taking that kind of action.

On the other hand, I think we have to remember what causes the problem. They cannot afford to buy the prescription drugs that they are being given by the physicians or their health care people, and so they are forced into taking this particular action.

What is the answer? Again, I feel like the answer is an affordable, accessible prescription drugs program under Medicare which would help both of these witnesses that we have heard from this morning.

Mr. ENGEL. Would any of the other witnesses—Ms. Coplan, would you like to comment on that at all?

Ms. COPLAN. Definitely there is a need. I feel that, and I know all my friends that are still with us feel it also. I do have this AARP, and with AARP I have to send away for the drugs, and then they tack on a shipping charge. So if you start to add up and figure out, I can't use my AARP pharmacy, I have to go elsewhere. I would like to put that into a question for you as to how we could change that, because it becomes more expensive again. And you could control the drugs.

Mr. LIPSCOMB. In that particular instance, I want to make clear for the record she is not sending outside the United States to get the drug. That is done in here, in the U.S., and we do centralized buying to run the price down. Ideally, it would seem to us that a program like Medicare that bought for 35 million people would be able to leverage more economy in terms of drug prices than AARP even would, so maybe that is something that we could look at in terms of programs.

Mr. ENGEL. Another thing that I get from seniors in my district, I also hear it from my mother here in south Florida is the disparity when you go to different pharmacies. I mean how much different? You would think it would all be within a few dollars, but you can pay as much as $10 or $15 or even $20 more from one pharmacy to the next. Ms. Coplan?

Ms. COPLAN. Yes, sir. The other day there was a program on television—I watch rarely but I watch this one—and if you go into a poor neighborhood, the drug prices go down. If you are in a more affluent neighborhood, the prices go up. There is no conformity there either.

Mr. GREENWOOD. If the gentleman would yield for a moment. And that is the global phenomena as well.

Ms. COPLAN. Yes.

Mr. GREENWOOD. In other words, the reason that drugs are less expensive in Mexico is because they are priced based on what the market will bear. And that is obviously different than it is in southern Florida. And then of course the difference in Canada, this

phenomena in Canada, is different entirely, because there the government controls the prices, and that is why you have this disparity. And I yield back to the gentleman and thank him for yielding to me.

Mr. ENGEL. No. I thank the chairman. What about if we on a Federal level are not—this is for Mr. Lipscomb—are not doing what people think we should be doing, what can the States do? Can the State attempt to certify that these walk-in entities are complying with certain standards? What do you think the State can be doing or the FDA, for that matter, to prevent consumers from being sold dangerous drugs or by just being ripped off by unscrupulous people?

Mr. LIPSCOMB. Thank you, Mr. Engel. I contacted Washington a couple weeks back inquiring about whose responsibility it was to assure the quality of the drugs, for instance, coming in from Canada. And, essentially, the answer I got was that they thought it was probably a State responsibility. And I pointed out that the last time I checked Florida did not have any offices either in New York State or Minnesota or any of the—going all the way across to Washington State.

Mr. ENGEL. Yes. I was going to say, not to cut you off, but it is obviously different. My home State of New York obviously has a border with Canada——

Mr. LIPSCOMB. Right.

Mr. ENGEL. [continuing] and there are a lot of drugs coming down through that border. But, obviously, Florida would be a different situation.

Mr. LIPSCOMB. Governor Patacki I am sure would probably hasten to clarify that he doesn't have any agents checking the quality of those drugs either. I mean I think that in the U.S. we rely on the Food and Drug Administration in these kinds of instances, and if they can't do it, then I guess my expectation would be that they would be coming to you gentlemen and saying, "We need legislation in order to protect the public." I haven't seen that taking place yet.

Mr. ENGEL. Well, how would we know that the drugs are even coming in from Canada? How do we know that they are not from China or some other place? I mean I think that seniors probably psychologically have some confidence in Canada, but when you are talking about drugs coming from the other side of the world, I think there is less confidence there. How do we even know the drugs are coming in from Canada?

Mr. LIPSCOMB. Well, I think that these two witnesses could probably answer that, because they are facing making those kind of decisions on a daily basis. But I think that Congressman Deutsch said a while ago, people get desperate. They have to do something, and so therefore they take chances that you and I might not take when we are not faced with those same kinds of decisions.

Mr. ENGEL. Well, unless anyone has any other comments, I will go back. I want to just thank my colleagues for their leadership in this role and hope that we can all put our heads together and sort it out in Washington.

Mr. GREENWOOD. The Chair thanks the gentleman. Ms. Coplan, you look like you want to show something.

Ms. COPLAN. I am sorry. Someone just handed me a paper. It says, "Cheap Drug Myths." Would you like to read it. I haven't read it.

Mr. GREENWOOD. Well, what we will do is we will——

Ms. COPLAN. Somebody just handed it to me.

Mr. GREENWOOD. [continuing] without objection, we will make it a part of the official record, and we will have one of our clerks collect that from you.

Ms. COPLAN. Okay.

[The information referred to follows:]

THE CHEAP DRUGS MYTH

CANADA IS OFFERED UP AS PROOF THAT PRICE CONTROLS WOULD DRAMATICALLY CUT THE COST OF MEDICINE. THE PROOF HAS SOME HOLES.

By Ira Carnahan

In Canada a Three-month prescription for Merck's cholesterol reducer Zocor goes for $172. In the U.S., patients who pay retail fork over $328 for the same pills. The media are full of such shocking comparisons aimed at demonstrating that Canadians, thanks to price controls, pay far less for medicine than do Americans. Just one problem: It isn't so. While some high-profile brand name drugs are much cheaper in Canada, other lesser-known drugs and generics are not. In fact, 21 of 27 top-selling generics cost more in Canada than in the US., reports a study of lowest available prices by Palmer D'Angelo Consulting, an Ottawa firm that works for branded drugmakers. For all 27 combined, the average Canadian premium is 37%. Why? Just two companies dominate the Canadian generics market, says study co-author Neil Palmer.

That lack of competition is, ironically, partly a side effect of Canadian drug-price controls. Generic makers find countries with controls on patented drugs less attractive. So fewer jump in when a branded drug goes off patent. The end result: In the U.S., generic drugs cost an average of 74% less than equivalent brand name drugs; in Canada, generics average just 38% less.

Canada's rules can also discourage branded drugmakers from discounting older drugs to compete. John R. Graham of the Fraser Institute in Vancouver explains why: Canada's Patented Medicine Prices Review Board typically sets the maximum price for a new drug by comparing it with similar drugs already on the market. So if companies lowered prices on old drugs, that could cut into profits on new ones, too.

How did the myth of cheap Canadian drugs gain such wide acceptance? It began with a 1992 study by Congress' General Accounting Office and was reinforced by a 1998 report from the Democratic staff of the House Committee on Government Reform. Both studies were flawed. They compared only top-selling brand-name drugs, ignoring lower-priced generics that now make up half of US. prescriptions. Furthermore, prices in the studies weren't properly weighted to reflect market share or volume discounts, argues Wharton School health economist Patricia Danzon. Correcting for such flaws, Danzon and Li-Wei Chao, also of Wharton, found that if Americans had paid Canadian prices for the drugs they bought in 1992, they would have saved, at most, 13%.

Yes, the Wharton economists have received research funding from the drug industry, and yes, the price break Canadians enjoy is has likely widened since 1992. But it's doubtful that Canada's price controls on patented drugs, as opposed to economics, are the main cause of lower prices there.

The truth is, notes the Fraser Institute's Graham, all kinds of goods cost more in the U.S. than Canada. A turbo Chrysler PT Cruiser retails for $23,100 in the U.S. and the equivalent of $17,800 up north. Yet there's no Canadian Retro Car Prices Review Board. Even bigger price differences are common for goods with high fixed costs but lower variable costs, everything from music CDs to online service. Prices are lower in Canada because incomes there are a fifth smaller and the Canadian dollar is weaker. Producers logically try to recoup most of their high fixed costs from wealthier consumers and charge those who can't pay as much a price closer to marginal cost.

There's another reason for lower drug prices in Canada: lower liability costs. In Canada, judges—not juries—typically set damages, and awards for pain and suffering are capped at $185,000 U.S. Such differences account for a third to a half of the gap, a 1997 study in the *Journal of Law and Economics* concluded. Yet the

politicians and do-gooders who complain most about U.S. drug prices are often the least likely to favor reining in legal costs.

Mr. GREENWOOD. Mr. Deutsch's staff spent some time yesterday at the Miami Airport looking at pharmaceutical products coming in, and it is a—and I have done this, Mr. Deutsch and I have done this at Dulles Airport in Washington. It bends the mind when you see the volume of drugs that come into this country through the airports from all over the world, and we see illegal substances, we see counterfeit substances, we see boxes of pills just loose. It is phenomenal and it is scary because we certainly know a couple of things. We know that in places like India and Thailand and China and elsewhere, the ability to create counterfeits that you cannot distinguish the container, the label, the pill itself are indistinguishable from the real product without any guarantee that what is in that pill is something other than chalk, for that matter. So it is a—there is a corruption out there that is being fed by this—being fueled by this huge unsolved problem that we have in the United States.

And so it will be our objective to—I think probably the most significant thing that we can do is provide the prescription drug benefit, make it a realistic one that the taxpayers can afford but make it one that really goes a long way to meeting the unmet needs. The problem with the FDA, as you referred to, is that they are just overwhelmed. I mean the FDA and the Customs people are so overwhelmed by the volume here, that it would be almost a shame to take resources that we should be using to provide prescription drugs and using them to try to stem this illegal tide. You had something else you wanted to say, Ms. Coplan?

Ms. COPLAN. No.

Mr. GREENWOOD. Okay. Well, in that case, I am going to thank the witnesses for coming. I would suggest that, Ms. Coplan and Mr. Sweed, if you want to, if you are able to, I think in the third panel we are going to have a witness who has taken a look at your specific prescriptions that you are needing now and your specific income situation and has done some calculations and looked at some of the programs to see how that would apply to you and hopeful that that will be helpful. So we are going to take about a less than 1 minute break now while we swap over panels.

Mr. SWEED. Thanks, Mr. Chairman.

Mr. LIPSCOMB. Thank you very much.

Mr. GREENWOOD. And thank you for being with us.

[Brief recess.]

Mr. GREENWOOD. Okay. We welcome our second panel. We are pleased to have with us Mr. John Taylor who is the Associate Commissioner of Regulatory Affairs at FDA, and we have Mr. John Taylor also who is a drug inspector with the Florida Department of Health, Bureau of Statewide Pharmaceutical Services. We thank both of you gentlemen for being with us.

You probably heard me say to the first panel that this is an investigative hearing, and it is our custom and practice to take testimony under oath. Do either of you have any objections to giving your testimony under oath? Okay. Then I should also advise you that pursuant to the rules of this committee and to the House of Representatives that you are entitled to be represented by counsel.

Do either of you wish to be represented by counsel? Okay. In that case, if you would stand and raise your right hands.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. We thank you. You are under oath, and, Mr. Taylor of the FDA, we will begin with you, and if you would summarize your testimony in about 5 minutes, we won't be strict with that, we would appreciate it. Thank you.

TESTIMONY OF JOHN M. TAYLOR, ASSOCIATE COMMISSIONER OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION; AND JOHN D. TAYLOR, DRUG INSPECTOR, FLORIDA DEPARTMENT OF HEALTH, BUREAU OF STATEWIDE PHARMACEUTICAL SERVICES

Mr. JOHN M. TAYLOR. Thank you very much. Thank you, Mr. Chairman, Congressman Deutsch, Congressman Engel. I am John M. Taylor, Associate——

Mr. GREENWOOD. Can you folks in the back of the room hear him? Okay. Just pull that microphone up nice and close. I think it is on, you just need to pull it up.

Mr. JOHN M. TAYLOR. Is that better?

Mr. GREENWOOD. Yes. It is very directional.

Mr. JOHN M. TAYLOR. Thank you. I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the United States Food and Drug Administration. I appreciate the opportunity to discuss our mutual concerns related to the importation of drugs into the United States. This discussion will focus on the importation by individuals of prescription drugs through the mail or in person with a specific focus on the purchase of drugs from foreign sources over the Internet.

Under the Federal Food, Drug, and Cosmetic Act, unapproved, misbranded and adulterated drugs cannot be imported into the United States. This includes foreign versions of United States-approved medications, as well as drugs that are made in the United States, exported to other countries and then subsequently reimported int the United States. For public health reasons, the FDA remains concerned about the importation of prescription drugs into the United States. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality.

The use of the Internet by our Nation's citizens has opened up vast new opportunities for the exchange of information. The Internet permits an increasing number of individuals to obtain a plethora of medical information. It also allows consumers to purchase drugs anonymously and for consumers who live in remote areas or have limited mobility, the Internet facilitates the purchase of products with relative ease. In some cases, the Internet also allows consumers to purchase drugs at cheaper prices. The fact that the Internet allows consumers to purchase drugs at cheaper prices is a trap to many consumers, including millions of seniors that are faced with steadily rising health care and prescription medication costs.

Accordingly, consumers, including America's seniors, are buying more and more of their prescription medications online rather than

from their local pharmacies. However, as beneficial as this technology can be, it also creates a new marketplace for activity that is already illegal. Furthermore, because the Internet is a worldwide communications system, U.S. citizens are now susceptible to illegal conduct from sources outside the United States as well as domestically. Therefore, FDA cannot assure the American public that the drugs imported from foreign countries are the same as products approved by the Food and Drug Administration.

FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from Internet sites that dispense foreign drugs or are not operated by pharmacies licensed and operated under State pharmacy law. These outlets may dispense expired, some potent, contaminated or counterfeit products. It could dispense the wrong or a contraindicated product, an incorrect dose or medication unaccompanied by adequate directions for use. In addition, FDA cannot provide consumers with any assurance that these products are manufactured under current good manufacturing standards or stored properly. Taking such unsafe or inappropriate medications puts consumers at a risk for dangerous drug interactions and other serious health consequences.

Another potential problem involves Internet sites that provide prescription drugs without a prescription or by having consumers fill out a questionnaire rather than seeing a doctor, a point that I think was underscored by the members of the first panel. A questionnaire generally does not provide sufficient information for a health care professional to determine if that drug is appropriate or safe to use, if another treatment is more appropriate or if the consumer has an underlying medical condition where using that drug may be harmful. Over the last 12 to 18 months, there has been a dramatic increase in the number of foreign web sites.

In addition, there has been a proliferation of storefront Internet prescription drug operations. These small stores, often located in busy strip malls, advertise that they can obtain cheaper drugs from Canada. Some Canadian web sites report to offer U.S.-approved drugs. However, it is highly unlikely that the drugs are in fact approved by FDA. Some web sites are actually ordering services that take orders from consumers that are then fulfilled by supposed Canadian pharmacies. Storefront pharmacies require a prescription from a doctor in the U.S. and then the prescription is sent to a Canadian pharmacy. In either case, American consumers cannot be certain that the drugs they receive are Canadian or United States approved, and, furthermore, under State law, these ordering services are likely participating in the practice of pharmacy without a license to do so.

A number of these web sites and storefront operations claim that drug sales from Canadian pharmacies to U.S. consumers for their personal use are legal. This is not true. The current personal importation policy permits the exercise of enforcement discretion to allow the entry of an unapproved prescription drug only if the product meets certain requirements. However, this does not mean that the importation of drugs for personal use is legal. Due to the huge volume of drug parcels entering the United States through the international mail and courier services, the requirements for notice and hearing and our limited resources, it is difficult for FDA

to detain and refuse mail imports for personal use. As a consequence, tens of thousands of parcels that FDA does not review are eventually released by Customs and sent on to their addressees, even though the products contained in these parcels may violate the act and impose a health risk to consumers. We do not believe this is an acceptable public health outcome.

FDA is taking a number of steps to address the potential safety concerns of illegally imported prescription medicines so that the public health of U.S. citizens is protected. These include educating the public to the possible safety issues of drugs purchased from foreign countries, working in conjunction with our Canadian government counterparts to address the issue of the flood of prescription medicines coming into the U.S. from their country and referring U.S. web sites to the Canadian government for investigation, increasing our enforcement and policing of rogue Internet sites and partnering with the individual U.S. States, including the State of Florida, to develop enforcement strategies, share cases and discuss important policy issues.

Moreover, we are reevaluating, refining and improving the programs and procedures that we are using to ensure the availability of safe and effective drugs to U.S. consumers. In addition, we are supportive of the National Association of Board of Pharmacy's Verified Internet Pharmacy Site Program and the State of Florida's efforts to publish a revised proposed rule that holds pharmacists accountable for ensuring that prescriptions that they receive have been written only after a patient evaluation, including a physical examination. Under Florida's proposed rule, those who fill prescriptions without a proof of a patient/physician relationship are subject to State sanctions.

Some recent civil and criminal as well as a number of administrative actions and enforcement correspondence illustrate the steps that FDA is taking to respond to Internet drug sales. A number of cases as well as a description of some of our cases is described in more detail in my written testimony. Needless to say, FDA, in conjunction with the Department of Justice, the Federal Trade Commission, Customs, Drug Enforcement Agency and other Federal, State, including the State of Florida, and international partners, have taken numerous civil and criminal actions against legal products and individuals who have used the Internet to engage illegal conduct.

In closing, Mr. Chairman, FDA remains concerned about any possibility that unsafe drugs may find their way into the American drug supply. We will remain vigilant as we refine and improve the programs and procedures that we use to ensure the availability of safe medications for consumers. We appreciate the subcommittee's interest in assuring that the American public has access to safe and affordable medicines, and we look forward to working with you in furtherance of this goal. Thank you again for the opportunity to participate in today's hearing, and I will be happy to answer any questions.

[The prepared statement of John M. Taylor follows:]

PREPARED STATEMENT OF JOHN M. TAYLOR, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Mr. Chairman, Ranking Member Deutsch and other Members of the Subcommittee, I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the U.S. Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to testify at today's hearing on "South Florida Access to Affordable Prescription Drugs: Costs and Benefits of Alternative Solutions" on behalf of FDA. My testimony will focus on FDA's efforts to assess and respond to the importation of prescription drugs by individuals through the mail or in person and the purchase of drugs from foreign sources over the Internet.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, it is unlawful to import unapproved, misbranded, and adulterated drugs into the United States. This includes foreign versions of U.S.-approved medications, as well as drugs that are made in the U.S., exported to other countries, and then subsequently reimported to the U.S.

For public health reasons, FDA remains concerned about the importation of prescription drugs into the U.S. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. The rise of Internet drugs sales presents substantial safety questions about these products. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.

Some of the efforts FDA is undertaking to address the potential safety concerns of illegally imported prescription medicines include: increasing consumer awareness of the potential risks associated with imported drugs, working with the states to crack down on Internet pharmacies selling illegal products, and undertaking further analysis of the quality of drugs coming into the U.S. from foreign sources.

News reports in the last few months have focused on storefront Internet prescription drug operations. These small stores, often located in busy strip malls, advertise that they can obtain cheaper drugs from Canada. Typically, the customer supplies the store operator with a prescription from an American physician and is asked to complete a medical questionnaire. This information is sent electronically to a Canadian wholesaler/supplier/contact that serves as a supplier to the store. A Canadian physician reviews the questionnaire and writes a Canadian prescription that is filled and shipped to the U.S. Usually the prescription drug is shipped directly to the customer's home. The storefront facilitates the transaction and typically does not receive shipments of drugs. The storefront charges a shipping and handling fee. The customer may purchase a product for substantially less than the price they would have paid otherwise.

FDA's concerns do not apply to all Internet pharmacies, as a general matter. Many online pharmacies operate in keeping with standards of state licensing authorities. FDA acknowledges that the Internet can be a useful source of health information and health care products and services. Internet pharmacies can have various benefits, including reduced prices, increased access (especially in rural areas), and enhanced consumer convenience. Rather, this testimony highlights the growing practice of using mail order and Internet pharmacies to facilitate potentially unlawful and unsafe importation of prescription drugs.

Under the FD&C Act, unapproved, misbranded, and adulterated drugs cannot be imported. The FD&C Act further prohibits the reimportation of FDA-approved drugs that are made in the U.S. and have been exported to other countries. Our specific activities and concerns relating to reimportation of drugs follows:

- **EDUCATION ABOUT SAFETY:** Consumers take genuine risks when they purchase drugs from Internet sites that dispense foreign drugs or are not operated by pharmacies licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication without adequate directions for use. Unsafe or inappropriate drugs put consumers at risk for dangerous drug interactions and serious health consequences.
- **WORKING WITH STATES:** Last month, we hosted a nationwide call with 38 state boards of pharmacy, other state regulatory agencies and consumer groups to discuss the current status of Internet drug sale practices. Some state laws are stronger than others, but we are actively engaged a number of states in jointly pursuing illegal Internet sites.
- **CANADIAN COOPERATION:** FDA is actively working with the Health Canada regarding the increasing number of U.S. pharmacies that are advertising and

promoting sales of prescription drugs from Canada. We have asked the Minister of Health to investigate a list of 45 Canadian websites that are selling drugs to U.S. citizens. We agreed to designate respective Agency contacts on this issue and continue our discussions about Internet sales.

- **ENFORCEMENT:** Recent criminal and civil cases are evidence of the seriousness of the risks to public health that regulators uncover when responding to Internet drug sales. These cases show that we are making progress in combating this problem. Examples include our actions against the Norfolk Men's Clinic, Medications Express in California, Pillbox Pharmacy and successful prosecutions against the operators of these and other Internet sites. To date, FDA has initiated:
  - 372 Internet drug investigations resulting in 150 Internet-related drug arrests and 92 convictions.
  - 100 open Internet drug investigations. Also, 90 sites are under active review for possible regulatory or civil action.
  - Nearly 200 cyber letters to domestic and foreign online sellers.
  - 5 preliminary injunctions.
  - 15 product seizures.
  - 11 product recalls, and the voluntary destruction of 18 illegal products.
  - Detention Without Physical Examination for the products of 45 foreign shippers.

HIGH COST OF PRESCRIPTION MEDICATIONS

It is estimated that Americans spend about $192 billion a year on prescription drugs, about twice as much as what they spent a decade ago. As new drugs are developed, Americans also are taking more drugs. Based on IMS Health and Department of Commerce data, the National Association of Chain Drug Stores (NACDS) states sales of retail prescription drugs grew by about 15 percent in 2002, 13 percent in 2001 and 16 percent in 2000. Mail order sales rose six-fold in the ten years from 1992 to 2001 and are positioned to pass independent pharmacies as the second largest provider of retail prescriptions by the end of 2003. Many consumers, including millions of senior citizens, are faced with steadily rising health care and prescription medication costs. It is estimated that about 80 percent of seniors take at least one prescription drug.

FDA is aware that developing and manufacturing medicines is expensive. Drug development is also time consuming and it may take as many as 10 years or more for a drug to transition from test tube to FDA approval. Drug companies estimate that it costs an average of $800 million to develop a new drug.

NEW WAYS TO BUY CHEAPER PRESCRIPTION DRUGS

The Internet is a major avenue of commerce and the volume of Internet sales, including prescription drugs, is growing dramatically. Consumers, including America's seniors, are buying more and more of their prescription medications online rather than from their local pharmacies. This practice is growing at an exponential rate and will likely continue.

Seniors who do not have access to a computer may nonetheless purchase drugs on line. In some areas of the country they simply visit a fee-for-service "storefront" location that will facilitate their Internet purchase and have their prescription medication mailed directly to their home.

Many of the drugs purchased over the Internet are being ordered from Canada. Drugs are cheaper in Canada; they often sell for as little as half of U.S. price of a given drug. In Canada drug prices are fixed, allowing the government to offer them to Canadian citizens at much lower rates than what U.S. citizens pay at pharmacies. Americans are taking advantage of the lower priced drugs available in Canada without having to travel there to get their prescriptions

LEGAL AND SAFETY ISSUES

Patients Face Genuine Risks

Based on a survey conducted in early 2000 by FDA's Office of Criminal Investigations (OCI) and a subsequent study by the General Accounting Office, there appears to be roughly 300 to 400 Internet sites selling prescription drugs to consumers, with approximately half located domestically and half located outside the U.S. FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from Internet sites that dispense foreign drugs or are not operated by pharmacies licensed under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contra-

indicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. FDA cannot provide consumers with any assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. Taking such unsafe or inappropriate medications put consumers at risk for dangerous drug interactions and other serious health consequences.

Another potential problem involves Internet sites that provide prescription drugs by having consumers fill out a questionnaire rather than seeing a doctor. In some cases, a questionnaire generally may not provide sufficient information for a health care professional to determine if that drug is appropriate or safe to use, if another treatment is more appropriate, or if the consumer has an underlying medical condition where using that drug may be harmful. Finally, in the case of foreign-based websites, if a consumer has an adverse drug reaction or any other problem, they have little or no recourse because the physical location or operator of the pharmacy often is not known or the seller is beyond the consumer's reach. FDA has little or no ability to take effective action against these foreign operators on behalf of U.S. citizens.

Over the last twelve to eighteen months, FDA identified a proliferation of websites that sell drugs purportedly from Canada directly to U.S. consumers. A number of these websites claim that drug sales from Canadian pharmacies to U.S. consumers are legal. This is false. Some websites are actually ordering services that take orders from consumers that are then filled by other pharmacies. In some cases, American consumers cannot be certain that the drugs they receive are being dispensed by the person from whom they are received.

A number of Canadian drug websites and U.S. ordering services indicate that the Canadian drugs are dispensed pursuant to existing prescriptions that are rewritten by a Canadian doctor in order to comply with Canadian law. However, the dispensing of medication on a prescription written by a physician who has not seen the patient or conducted a physical exam is contrary to state medical practice standards. In addition, Dr. Henry Haddad of the Canadian Medical Association has said that under the Canadian Code of Ethics, physicians have a responsibility to do a patient history, conduct a physical exam and discuss the risks and benefits of the medication with the patient.

In general, FDA has no information to establish where these drugs were actually manufactured and whether cGMP requirements were followed. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. There is no assurance that the drugs are not counterfeit, contaminated or misbranded. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination.

Serious legal issues

In a February 12, 2003, letter to The Kullman Firm, New Orleans, Louisiana, FDA clearly stated the Agency's safety and legal concerns about the importation of prescription drugs from Canada, stating that many of these drugs are of unknown quality. From a legal standpoint, businesses and individuals involved in shipping prescription drugs from Canada or other foreign countries to consumers must take many steps to ensure compliance with the FD&C Act. In most cases, it is unlikely that these legal requirements have been met.

The FD&C Act establishes a legal framework applicable to imports of prescription drugs from Canada. As a result, virtually all drugs imported from Canada by or for individual U.S. consumers violate U.S. law. Such drugs are unapproved (21 U.S. C. § 355), misbranded, labeled incorrectly (21 U.S.C. § 353(b)(2)), and /or dispensed without a valid prescription (21 U.S.C. § 353 (b)(1)). Thus, their shipment into the U.S. from Canada violates the FD&C Act *See e.g.* 21 U.S.C. 331(a), (d), (t). In addition, it is a violation of the FD&C Act for anyone other than the U.S. manufacturer of a drug to import into the U. S. (21 U.S.C. § 381 (d)(1)), even if the drug was approved and manufactured in the U.S.

Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. because FDA approvals are manufacturer-specific, product-specific and include many requirements relating to the product, such as the location of the manufacturing site, formulation, source, specifications of the active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Title 21, *Code of Federal Regulations* (21 CFR) § 314.50. Drugs sold outside of the U.S. are frequently not manufactured by a firm that has received FDA approval for that particular drug. In addition, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all the requirements for U.S. approval, and FDA considers it to be unapproved. 21 U.S.C. § 355.

In order to ensure compliance with the Act when shipping prescription drugs to consumers in the U.S., businesses and individuals must ensure, among other things, that they only sell FDA-approved drugs that are made outside of the U.S. and that comply with the FDA approval in all respects including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 CFR ◆314.50. They must ensure that each drug meets all U.S. labeling requirements, including that it bears the FDA-approved labeling. 21 CFR § 201.100 (c)(2). The drug must also be dispensed by a pharmacist pursuant to a valid prescription. 21 U.S.C. § 353(b)(1).

STEPS FDA IS TAKING TO PROTECT PUBLIC HEALTH

FDA cannot assure U.S. citizens that the prescription medications they are buying over the Internet from foreign countries such as Canada are safe. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S. approved prescription drugs are, in fact, of unknown quality. The rise of Internet drugs sales presents substantial safety questions about these products.

FDA is taking a number of steps to protect the public health of U.S. citizens including: (1) educating the public to the possible safety issues of drugs purchased from foreign countries, (2) working in conjunction with our Canadian government counterparts to address the issue of the flood of prescription medicines coming into the U.S. from their country, (3) increasing enforcement and policing of rogue Internet sites, and (4) partnering with the individual U.S. states to develop enforcement strategies, share cases and discuss important policy issues.

Consumer education

FDA remains committed to developing more effective education and enforcement strategies. With this goal in mind, FDA has created brochures and posters entitled: *Things you should know about purchasing medications outside the United States* to alert consumers to the health risks of buying medications outside the U.S. Outreach to consumers and the press continues and new public material will be added to FDA's website.

In December 2000 FDA created the "Buying Medicines Online" webpage; http://www.fda.gov/oc/buyonline/default.htm. The webpage provides tips, warnings and other information for consumers about purchasing over the Internet. In addition, it provides an opportunity for consumers to report unlawful sales of medical products on the Internet. Since its inception, the number of complaints received has grown steadily. FDA receives over 300 reports a day through this webpage that are evaluated by members of an FDA Internet enforcement work group.

A voluntary certification program administered by the National Association of Boards of Pharmacy called the Verified Internet Pharmacy Practice Sites (VIPPS) program provides a basis for identifying online pharmacies that are appropriately licensed and prepared to practice pharmacy via the Internet. Today 13 Internet sites representing over 10,000 pharmacies carry the VIPPS seal, and NABP has many pending applications.

Canadian cooperation

On February 21, 2003, FDA representatives participated in a Forum on International Sale of Prescription Drugs from Canada in Ottawa, Canada. The forum was sponsored by the National Association of Pharmacy Regulatory Authorities (NAPRA), the voluntary umbrella association of Canada's provincial and territorial pharmacy licensing bodies.

FDA's purpose in attending was to present our view on the sale of Canadian prescription drugs in the U.S. Some of the topics that related to FDA enforcement included: the need for clarification of legal status of international practice in the U.S., the legality of the sale of Canadian drugs to U.S. citizens, risks of the activity for U.S. and Canadian citizens, the legal recourse for any harm caused, the legal issues within the U.S. (at the Federal and state level) and the need to investigate and shut down non-pharmacy operations selling prescription drugs.

In February 2003, FDA Commissioner McClellan participated in a call with Health Canada to discuss his concerns regarding the increasing number of U.S. pharmacies that are advertising and promoting prescription drugs from Canada. FDA shared a list of 45 active websites based in Canada that are selling drugs to U.S. citizens for additional investigation.

FDA work with states

The states have primary jurisdiction over the practice of pharmacy. FDA is partnering with the states in pursuing cases. State pharmacy laws vary in all 50

states. FDA notes that some state laws are stronger than others and some states have been more willing to pursue these cases than others.

In February 2003 the ORA Division of Federal State Relations hosted a nationwide call with state boards of pharmacy, other state regulatory agencies and consumer groups to discuss the current status of information on Internet drug sale practices. Representatives from 38 states participated in the discussion. FDA was interested in hearing about state policy issues and regulatory actions. In addition, FDA had the opportunity to share information with the states on current regulatory policy and consumer education efforts on this issue.

Increased Federal and International enforcement activities

FDA remains concerned about the potential for introduction of substandard drug products into the U.S. through foreign Internet purchases. As such, FDA has been participating in quarterly strategy meetings with other Federal counterparts including Federal Trade Commission (FTC), Department of Justice (DOJ), National Association of Attorneys General (NAAG) and Drug Enforcement Administration (DEA). In these meetings FDA discusses policy matters, public information issues and Agency priorities. This quarterly monthly meeting dates back to 1998. FDA and FTC continue to work together on false and deceptive claims about treating or curing a wide variety of diseases. FDA and other Federal and state agencies have investigated many illegal pharmaceutical websites and have attempted to use existing laws and available technologies to bring action against rogue Internet pharmacies.

In June 1999, FDA established a case assessment, or "triage" team with representatives from the Office of Enforcement and the Office of Criminal Investigation (OCI) within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of the Chief Counsel (OCC) and the Office of Policy. Under the "triage" process, FDA obtains leads on potentially violative sites from a variety of sources including Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, and the press. The "triage" team evaluates the leads and decides whether they should initially be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The "triage" team makes referrals, when appropriate, to FDA's civil and criminal enforcement units for follow-up.

FDA receives over 300 messages per day in its Reporting Unlawful Sales of Medical Products on the Internet system. In 2002, FDA linked to the FTC Consumer Sentinel database to help cope with the large number of complaints it receives. The Consumer Sentinel database, maintained by FTC, contains more than one million consumer fraud complaints that have been filed with Federal, state, and local law enforcement agencies and private organizations. Through this law enforcement data base system, FDA is able to mine the data in this system and obtain useful information on Internet pharmacy sites of particular interest.

FDA Office of Criminal Investigations activities

Because FDA and the other Federal agencies possess limited investigatory jurisdiction over sellers in foreign countries, we must work with foreign governments to bring action against such individuals. Internet crime and the practice of online pharmacy are a growing concern throughout the international law enforcement community. FDA's OCI maintains ongoing liaison with numerous government agencies in Canada, the United Kingdom, Spain, Australia, Germany, Belgium, the Netherlands, Ireland, Brazil, Singapore and others. OCI recently assigned a Special Agent to Interpol in Washington, D.C.

An example of this cooperation involved OCI contact with authorities in a Pacific Rim country where a website operator alleged that he used the services of two legitimate doctors to review his online questionnaire. Through our foreign counterparts, we were able to have the doctors interviewed. Both denied any involvement in the scheme, thus exposing the operator to possible mail and wire fraud or other charges.

OCI routinely works on joint investigations with numerous law enforcement agencies throughout the Federal community including: the Federal Bureau of Investigations, U.S. Customs, DEA, U.S. Postal Service, Internal Revenue Service, Health and Human Service-OIG, EPA and the U.S. Army. In addition, OCI has worked on joint cases involving Internet pharmacies with several state entities including state health departments, state pharmacy boards, and state medical boards. OCI has established collegial working relationships with state entities nationwide.

Some recent cases indicate the seriousness of the risks to public health that regulators uncover when responding to Internet drug sales. They also illustrate the progress that is beginning to be made in combating this problem.

Norfolk Men's Clinic

On February 16, 2002, a Federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of the online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA. From fall 1998 to the summer of 2000, the defendants operated a website called Viagra.au.com, also known as Norfolk Men's Clinic, and related sites, that sold a variety of prescription medications.

In September 1999, OCI received information regarding the Norfolk Men's Clinic and the website. Based on this information, several covert purchases were made via the Internet. Search warrants were executed in October 1999 that resulted in the seizure of prescription drugs and business records. Additional covert purchases were made. Based on these purchases and numerous interviews, several individuals were indicted. In addition to defendants Pusztai and Yates, the president of a prescription drug wholesaler located in Miami, Florida, and the company itself, pled guilty to distributing misbranded drugs. The company plead guilty to obstruction of justice. In conjunction with the indictment, a second search warrant was executed in Clanton, Alabama, along with two search warrants in West Virginia. While most of the drugs sold in this operation were domestic product, some appeared to have originated in New Zealand.

Dr. Mario Alvarez-Valentin

On January 11, 2002, Dr. Mario Alvarez-Valentin was sentenced to 26 months imprisonment after pleading guilty to wire fraud in connection with the unlawful sale of Viagra over the Internet. Alvarez was a physician contracted with Internet websites for the purpose of authorizing prescriptions for Viagra to persons throughout the U.S. From April 2000 to January 2001, Alvarez, who was only licensed to practice in Puerto Rico, prescribed and caused to be prescribed more than 4,000 prescriptions for Viagra. In doing so, he violated the licensing laws of at least 20 states. *United States v. Alvarez-Valentin,* D.P.R.

Kwikmed

On October 1, 2002, a Federal Grand Jury in Arizona returned a 198 count indictment against Kwikmed, Inc., Cymedic Health Group, Inc., four owners of these corporations, and two physicians associated with the corporations. The indictment alleges that defendants operated Internet websites, two of which include kwikmed.com and cymedic.com, through which they sold prescription drugs, including Viagra, Celebrex, Xenial, and Propecia. The websites did not require a consumer to have a prescription before receiving the drugs, instead the customers were required to complete a questionnaire, which the website told customers would be reviewed by a physician. Customers were charged a fee for this purported medical consultation. The indictment alleges, however, that for the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. The indictment also alleges that defendants repackaged drugs obtained from a drug wholesaler, even though defendants were not a registered manufacturer or a licensed pharmacy, and that there was never a licensed pharmacist in any way involved. The indictment also alleges that the drugs dispensed were adulterated because of the defendants' failure to follow cGMP in packaging, holding, and labeling of the drugs. The indictment alleges that during the course of the conspiracy the defendants and others generated sales in excess of $28 million, which was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. These sales resulted from the defendants' distribution of at least 48,816 new orders for prescription drugs and 41,817 refills of those orders. The indictment charges defendants with several violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

United States v. Carl David Roberts, (E.D. Tenn.).

On January 15, 2003, Roberts was sentenced to a prison term of 57 months. Roberts was chief administrator of an Internet business that used sophisticated technology to sell prescription drugs, including Schedule II narcotics, without any medical supervision. He had directed an organization that sold drugs from within the U.S., and from abroad. His organization included drug suppliers from Mexico, the Netherlands, and Ecuador. In September 2002, he pled guilty to distribution of controlled substances and conspiracy to violate the FD&C Act.

United States v. Kimball, (11th Circuit).

On May 14, 2002, the Eleventh Circuit affirmed the district court's sentence. Kimball received a 13-year sentence for violating the FD&C Act. Kimball was found guilty after trial of putting prescription drugs into commerce without a prescription. His marketing efforts included use of the Internet.

Medications Express

On June 7, 2001, Gerald Bevins was convicted in U.S. District Court for the Southern District of California of conspiracy to defraud the U.S. and commit offenses against the U.S. by introducing misbranded drugs into interstate commerce and smuggling. On September 4, 2001, Bevins was sentenced to serve twenty-four months in prison. The case was initiated on information received from Customs concerning an Internet website called Medications Express. Bevins sold Mexican prescription pharmaceuticals from this website and claimed that no doctor's prescription was necessary. He continued to sell Mexican prescription pharmaceuticals through the mail from Sun City, California, even after discontinuing the Medications Express website. Bevins, his wife and daughter would receive orders via mail, travel to Tijuana, Mexico, to purchase the pharmaceuticals, and smuggle them back into the U.S. The three packaged the pharmaceuticals into commercial courier boxes and shipped them to customers around the U.S. The drugs supplied by Bevins were labeled in Spanish.

Canadian Drug Store, Inc.

On May 14, 2002, the Ontario College of Pharmacists, a Canadian government agency, filed charges under Ontario law against The Canadian Drug Store, Inc., for unlawfully operating an unlicensed pharmacy and using an un-registered pharmacist in filling prescriptions for U.S. residents. The College also filed charges against a licensed pharmacist, pharmacy, and physician in Ontario for helping to facilitate the delivery of prescription and non-prescription drugs to U.S. residents. A drug wholesaler was charged with supplying medications to a non-licensed pharmacy.

According to a statement released by the College, there are many websites selling prescription and non-prescription medicines that have not been accredited as legitimate pharmacies by pharmacy regulators in either Canada or the U.S. Some websites presenting themselves as online "pharmacies" or "drugstores" may be operating without a pharmacy license and dispensing prescriptions without the oversight of a licensed pharmacist.

Total Remedy/Prescription Center II

According to news accounts, a Los Angeles pharmacy and two pharmacists were assessed penalties of almost $90 million in a California Board of Pharmacy proceeding in May 2002 for filling more than 3,500 illegal prescriptions over the Internet. The case was brought under a state law that creates a requirement to fill a prescription pursuant to a good-faith medical examination. The Internet site concentrated on filling prescriptions for lifestyle drugs such as Viagra and Propecia (Associated Press, 5/29/02).

Pillbox Pharmacy

In March, 2002, a Texas pharmacist, three doctors, two corporations and an individual were charged in a Federal indictment alleging that they conspired to illegally dispense drugs in connection with an Internet pharmacy operation. The indictment charged one pharmacist, three physicians and two corporations, the S&H Script Shop and the Pillbox Medical Center, with conspiring to illegally dispense controlled substances and commit money laundering. According to the indictment, between January 1, 2000, and June 12, 2001, the defendants grossed more than $7.7 million from the Internet sales of just two drugs alone. The indictment alleges the doctors would issue prescriptions without establishing a patient history, performing a mental or physical exam, using appropriate diagnostic or laboratory testing, or providing any means to monitor medication response. The charges were the result of an 18-month investigation by FDA, DEA and IRS, working with the U.S. Attorney's office. In April, the pharmacist and two corporations pled guilty to illegally dispensing controlled substances, and agreed to forfeit $1 million.

Other OCI Enforcement Activity

To date, OCI has initiated 372 Internet drug investigations with each case involving a variable number of websites from one to 25 or more. These cases originated from multiple sources including interception at mail facilities, web-based research, consumer complaints, and a variety of other sources. OCI has affected 150 Internet-

related drug arrests and obtained 92 convictions. Sixty of the Internet drug arrests and 26 of the convictions are Internet pharmacy related.

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 55 domestic online sellers. Additionally, FDA has sent 137 cyber letters to operators of Internet sites in many countries, including Canada, that offer to sell on-line prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. FDA also sends copies of its cyber letters to the home governments of targeted websites when the locations can be identified. However, follow-up depends on the ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

In cooperation with DOJ, FDA has obtained five preliminary injunctions against the sale of illegal products, including one product marketed as a weight-loss aid containing a potent thyroid hormone that could cause heart attacks or strokes, and an unapproved cancer therapy. Also, 15 product seizures, 11 product recalls, and the voluntary destruction of 18 illegal products have been achieved, generally pertaining to unapproved new drug products. Forty-five foreign shippers have been placed on Detention Without Physical Examination and added to an FDA Import Alert for targeting sales of unapproved new drug products to the U.S.

FDA's personal importation policy

FDA's personal importation policy is often misunderstood. Under FDA's personal importation policy, FDA inspectors may exercise enforcement discretion in limited circumstances to permit the importation of certain unapproved prescription medication for personal use.

First adopted in 1954, the policy was last modified in 1988 in response to concerns that certain potentially effective treatments for AIDS patients were not available in the U.S. but were available in other countries. The Agency expanded the guidance for humanitarian purposes to allow individuals suffering from serious medical conditions to acquire medical treatments legally available in foreign countries but not approved in the U.S.

The policy is not a license for individuals to import unapproved, and therefore illegal, drugs for personal use into the U.S. Because the policy does not apply to medications that are already available in the U.S. (even if sold under the same name), only a very few drug products available from Canada and Mexico and other foreign sources meet the personal importation criteria.

The current personal importation policy permits the exercise of enforcement discretion to allow entry of an unapproved prescription drug only if the product meets the following requirements: the intended use is for a serious condition for which effective treatment may not be available domestically; the product is considered not to represent an unreasonable risk; the product is for personal use; there is no known commercialization or promotion to U.S. residents by those involved in the distribution of the product; and the individual seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the U.S.-licensed doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

FDA's personal importation policy, as written, is difficult to implement with respect to mail shipments of drugs. This is due, at least in part, to the difficulty faced by Customs or FDA inspectors, or even health care practitioners, in identifying a medicine simply by its appearance or its labeling, which may falsely identify a product. From a practical standpoint, FDA inspectors cannot visually examine drug products contained in a mailed parcel and accurately determine their identity or the degree of risk posed to the individual who will receive these drugs.

Carson mail study

In early 2001, FDA and Customs conducted a survey of imported drug products entering the U.S. through the Carson City, California mail facility (the Carson pilot). The purpose of the Carson pilot was to examine incoming mail shipments of pharmaceutical products over a specified time frame to identify both the volume and the types of drug products entering the U.S. We also wanted to better assess the level of effort and human resources required to handle drug importations at a mail facility, and to better understand the public health implications these importations may have for U.S. consumers.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week, a much higher staffing level than is normally possible. Although Customs took a baseline sample which indicated they could have set aside for FDA review an estimated total of 16,500 international packages (650 packages per day), FDA was able to examine only 1,908 packages during the five-week pilot, or an average of 381 packages per week. Unexamined packages were sent on to the addressees. Of the 1,908 packages examined by FDA, 721 parcels (38 percent of the total) originating in 19 countries were detained and the addressees notified that the products appeared to be unapproved for use in the U.S., misbranded and/or a drug requiring a doctor's prescription.

Analysis of the Carson Pilot Drug Parcels

FDA's Center for Drug Evaluation and Research (CDER) reviewed listings of the products detained during the Carson pilot to define better the nature of the risk to public health from the types of products coming into the U.S. through personal importation. CDER's review demonstrates that there are serious public health risks associated with many of the 721 drug shipments (composed of 197 different drugs) detained at Carson. There are primarily two types of risks that consumers of these drugs would face. The first risk arises when consumers take drugs of unknown origin or quality. Second is the very significant risk associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.

In general, FDA has no information to establish where these drugs were actually manufactured and whether current GMP requirements were followed. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination. Approximately eight percent of the shipments contained drugs that could not be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

Several drugs do not appear to correspond with any FDA-approved drugs and therefore the risks associated with the products are difficult to assess. One drug had been reviewed for FDA approval but was rejected because its efficacy could not be demonstrated. Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market.

The vast majority of the shipments were identified as containing prescription drugs. A number of controlled substances were also identified. Importation of these drugs containing controlled substances violates criminal provisions of the Controlled Substances Import and Export Act, including 21 U.S.C. 960 (unregistered importer/declared importation). These drugs have the potential for abuse, addiction or risk of life-threatening overdose. A physician's prescription and oversight are essential for managing these risks. Additionally, drugs to treat diseases including diabetes, hypertension and serious infection were included in the Carson shipments, as were many drugs with serious contraindications and/or possible drug or food interactions.

Many of the drugs identified in the Carson pilot are intended to treat conditions that only physicians can properly diagnose. Consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits. For example, almost ten percent of the shipments were for antibiotics, despite the fact that consumers are generally not able to diagnose whether their symptoms are caused by bacterial or viral infections.

Enforcement at the border

Within the last two years, FDA has conducted three surveys at U.S. borders to gather data on drug products carried by individuals entering the U.S. While these border surveys involve land traffic rather than mail importation, the results show some similarities to the findings from the Carson mail pilot, but also some significant differences.

Southwest Border Survey (August 2000)

A survey of prescription drugs being brought by pedestrians into the U.S. at eight ports-of-entry along the 2,000-mile border with Mexico was conducted by FDA's Southwest Import District (SWID) with the assistance of other agencies. The survey looked at activity during four hours on a Saturday (August 12, 2000) at eight border ports in California, Arizona, and Texas. The purpose of the survey was to determine what specific types of products are being imported, and who is importing these products. The data collected from over 600 interviews indicated that the most common importers were bringing back primarily antibiotics or pain relievers. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions

while 41 percent were Mexican). While many of these products are already available as FDA-approved drugs in the U.S., some are unapproved for sale in this country.

Canadian Border Survey

On January 6, 2001, in cooperation with Customs, FDA conducted a survey to obtain a snapshot of prescription drug products being brought into the U.S. from Canada via passenger vehicles. During the eight-hour survey at three ports-of-entry in New York, Michigan and Washington, a total of 10,374 passenger vehicles and 58 buses crossed into the U.S. Of these, 33 passenger vehicles (35 individuals) were referred by Customs to be interviewed. These individuals brought in a total of 47 containers of drug products from Canada. The largest group of products was pain medicines. The next largest group of products was herbal products, with the reason for importation being that the products were not available in the U.S. Some of these drugs are unapproved foreign versions of FDA-approved drugs, although some approved for sale as prescription drugs in the U.S. are sold as over-the-counter medications in Canada.

Southwest Border Survey (April 2001)

On April 11, 2001, FDA, Customs, and other agencies conducted a survey of prescription drugs being brought into the U.S. at seven ports-of-entry along the U.S./Mexican border. During the four hour survey, a total of 586 persons imported in a total of 1,120 drugs. Approximately 56 percent had a prescription for the medicines (61 percent were U.S. prescriptions, 39 percent were Mexican). As in the earlier survey, many of these products are already available as FDA-approved drugs in the U.S., while some are unapproved for sale in this country.

Newly revised import alert

On December 9, 2002, FDA reissued import alert 66-41 to include certain drugs approved for restricted use (due to safety concerns) in the U.S. This import alert allows FDA district field investigators to automatically detain without examination the listing of drugs. The Agency has posted this special alert on its home page warning consumers that certain restricted distribution drugs should not be purchased over the Internet. FDA has also put these restricted distribution drugs on Import Alert, informing the Agency's import inspectors that shipments of these drug are not appropriate for admission into this country under FDA's personal importation policy. FDA has also specifically informed Customs about the fact that these dangerous drugs should not be admitted. Imported drugs subject to this import alert are not admissible under FDA's personal importation policy.

The FDA field guidance for this Import Alert provides that release of an unapproved drug for personal use may be appropriate if, among other considerations, the drug is intended for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means, and it is not considered to represent an unreasonable risk. The guidance is intended to apply only to: (1) persons who have received treatment in a foreign country with an unapproved drug that is not available in the U.S., and who, upon returning to the U.S., have imported the drug for their personal use in an effort to continue the treatment started abroad; and (2) persons who have made their own arrangements for obtaining an unapproved drug from foreign sources, when the drug has not been promoted in the U.S.

CONCLUSION

Mr. Chairman, FDA remains concerned about Americans purchasing prescription medicines over the Internet and whether this practice results in products being unlawfully imported into the U.S. We appreciate the subcommittee's interest in assuring that the American public has access to safe and affordable medicines and we look forward to working with you in furtherance of this goal. Thank you again for the opportunity to participate in today's hearing. I will be happy to answer any questions.

Mr. GREENWOOD. We thank you for being here.

Mr. Taylor of the Florida Department of Health.

STATEMENT OF JOHN D. TAYLOR

Mr. JOHN D. TAYLOR. Thank you, Mr. Chairman, Congressman Deutsch, Congressman Engel. My name is John D. Taylor. I recently accepted a position as a drug inspector with the Florida Department of Health's Bureau of Statewide Pharmaceutical Services.

For the previous 13 years, I was the executive director of the department's Board of Pharmacy. Thank you for the opportunity to discuss affordable prescription drugs. Availability of affordable prescription drugs is a priority for the department and our State's residents. However, there are several emergent issues involving Internet prescription drugs that are causing increasing concern.

The primary mission of the department is to promote and protect the health and safety of all people in Florida through the delivery of quality public health services and the promotion of health care standards. Pursuant to this mission, the department is concerned about the efficacy and safety of Internet prescription drugs.

The Division of Medical Quality Assurance is charged with the investigation of civil complaints involving illicit storefront activities. Although consumers to date have filed no complaints, several licensed pharmacies began filing complaints last year. The Department has begun aggressively pursuing these allegations of unlicensed pharmacy behavior and alleged illicit distribution of prescription drugs. Several investigations are currently underway. Disposition of these cases and possible referral to law enforcement for criminal complaint investigation are pending. As these are active investigations, I am not in a position to provide specific details at this time.

The Board of Pharmacy is composed of individuals licensed in the profession, as well as consumer members. The board is responsible for creating professional standards as well as determining probable cause in disciplinary actions involving the misconduct of pharmacy licensees. Currently, the Board of Pharmacy has proposed administrative rule in the area of Internet prescriptions. This proposed rule is now in the public comment period. Previous versions of this proposal have been delayed by challenges, and the current version addresses issues raised by an administrative judge. The revised rule may become effective in the next 2 to 3 months.

I will now focus on the first of two specific areas of concern: The practice of prescribing and dispensing prescription drugs via the Internet. As you know, Internet web sites are available that let consumers select and order prescription drugs. This international process is complex and difficult to investigate. First, the consumer submits a brief, online medical questionnaire, which seeks to determine suitability of the consumer for the medication. Then, if the consumer's request has not been disqualified based on their answers to the questionnaire, a prescription is issued by a prescriber associated with the web site. The issued prescription is then transmitted to a pharmacy associated with either the site or the prescriber.

The concerns with this process are numerous. There is no guarantee that the consumer has been truthful in completing the questionnaire. Likewise, there may be no quality oversight for the prescriber, the pharmacist that completes the prescription, the pharmacy itself or the product delivered to the consumer. If these drugs originate from a foreign country, there is a strong likelihood that the drugs themselves may not have been approved by the Food and Drug Administration. The department has investigated pharmacies that received over 300 prescriptions from a sole contracted physician in a single day—physicians that see regular patients during

their workday. Clearly, this is a serious issue. The position of the Department and various licensure boards, including the Boards of Medicine, the Board of Osteopathic Medicine, Dentistry, Podiatry and Nursing, is that prescribing based solely on an Internet questionnaire is below the standard of practice. Such a rule of the Board of Osteopathic Medicine has been challenged and upheld before a Florida administrative law judge. The department and the Board of Pharmacy believe that prescriptions issued in this manner are invalid. Pharmacies and pharmacists knowingly dispensing prescription drugs prescribed in this manner should be subject to discipline.

The licensure boards are in the process of promulgating rules to specifically preclude these activities. In some cases disciplinary action has been taken based on existing statutes and rules with varying levels of success. Department Secretary Dr. John Agwunobi has created a task force of representatives of the various licensure boards to study areas where there may be synergies for collective board actions with respect to Internet prescriptions.

The second issue I would like to discuss is the use of unlicensed facilities, so-called storefronts, that serve as middlemen for foreign prescription drug distribution. Foreign pharmacies are dispensing prescription drugs by mail to Florida residents. Existing operations usually include Canadian pharmacies, but recent calls to our office indicate that a site or facility using Mexican pharmacies may also be involved. Florida residents are drawn via advertising to locations where prescriptions issued by licensed Florida prescribers are solicited and accepted for transmission to these foreign pharmacies. These storefront locations are not licensed as pharmacies and do not meet minimum requirements for licensure under their current method of operation.

A consumer with a licensed prescriber's prescription visits the storefront and provides the prescription and credit card information to the storefront operator. The prescription is then faxed to a Canadian physician who rewrites the original prescription and then submits the new prescription to a Canadian pharmacy. The pharmacy prepares the drugs, which are then dispensed and mailed to the consumer's home in Florida. Similar to the concerns with Internet prescription dispensing, there are no guarantees that these drugs are FDA approved and there is no way to be certain of the drug's origin or history. The importation of prescription drugs in this manner is a violation of State and Federal laws.

Additionally, Florida statutes require licensure of non-resident pharmacies shipping prescription drugs to consumers in Florida. This Florida law provides for the licensure of non-resident pharmacies licensed in another State, but does not reference foreign pharmacies. In addition, Florida administrative code sections require a pharmacy permit for locations maintained from, "from which to solicit, accept or dispense prescriptions." Florida statutes also designate the unlicensed practice of pharmacy as a misdemeanor of the first degree. Since unlicensed activity carries the potential for criminal sanctions, it is outside the jurisdiction of the department's Board of Pharmacy to investigate or prosecute. In cases where an investigation shows evidence of unlicensed activity, referral for criminal prosecution or civil action will be considered

by the department. Closure of existing storefront operations will depend on the result of those investigations.

We know that the cost of vital prescription drugs is more than a significant issue for many of our residents. The department shares their concerns on this issue. However, many, if not all, of the products ordered from foreign sources require a liability waiver prior to delivery. This particular system, while less expensive for the consumer, bypasses regulatory safeguards and places them at greater health risks.

Again, this is a complex and evolving problem that crosses many jurisdictional boundaries with both national and international implications. The department is committed to addressing this safety issue and look forward to partnering with our Federal counterparts to ensure continued safe and effective prescription drugs for our residents. We are dedicated to ensuring secure access to prescription drugs and applaud Federal efforts along these lines. Undertaking an educational campaign to explain the safety concerns associated with this practice is a good first step in highlighting this issue for our residents and to allow for informed decisionmaking.

Thank you for the opportunity to speak, Mr. Chairman.

[The prepared statement of John D. Taylor follows:]

PREPARED STATEMENT OF JOHN D. TAYLOR, FLORIDA DEPARTMENT OF HEALTH

Mr. Chairman and Members of the Committee, my name is John D. Taylor. I recently accepted a position as a Drug Inspector with the Florida Department of Health's (FDOH) Bureau of Statewide Pharmaceutical Services. For the previous thirteen years, I was the Executive Director of FDOH's Board of Pharmacy.

Thank you for the opportunity to discuss affordable prescription drugs. Availability of affordable prescription drugs is a priority for FDOH and our state's residents. However, there are several emergent issues involving internet prescription drugs that are causing increasing concern.

FLORIDA DEPARTMENT OF HEALTH

The primary mission of FDOH is to promote and protect the health and safety of all people in Florida through the delivery of quality public health services and the promotion of health care standards. Pursuant to this mission, FDOH is concerned about the efficacy and safety of internet prescription drugs.

Division of Medical Quality Assurance

The Division of Medical Quality Assurance is charged with the investigation of civil complaints involving illicit storefront activities. Although consumers to date have filed no complaints, several licensed pharmacies began filing complaints last year. The Bureau of Statewide Pharmaceutical Services and the Division of Medical Quality Assurance (both within FDOH) have aggressively begun pursuing these allegations of unlicensed pharmacy behavior and alleged illicit distribution of prescription drugs. Several investigations are currently underway. Disposition of these cases and possible referral to law enforcement agencies for criminal complaint investigation are pending. As these are active investigations, I am not in a position to provide specific details at this time.

Board of Pharmacy

The Board of Pharmacy is composed of individuals licensed in that profession, as well as consumer members. The board is responsible for creating professional standards as well as determining probable cause in disciplinary actions involving the misconduct of pharmacy licensees.

Currently, the Board of Pharmacy has proposed "Standards of Practice for Filling Prescriptions Authorized by Practitioners Licensed in Jurisdictions Other than Florida or Procured Through the Internet" (64B16-27.833—attached). These standards are now in the public comment period. Previous versions of these standards have been delayed by challenges, and the current version addresses issues raised by an administrative judge. The revised standards may become effective in two to three months.

INTERNET PRESCRIBING AND DISPENSING

I will now focus on the first of two specific areas of concern: the actual practice of prescribing and dispensing prescription drugs via the Internet. As you know, Internet websites are available that let consumers select and order prescription drugs. This international process is complex and difficult to investigate.

First, the consumer submits a brief, online medical questionnaire, which seeks to determine suitability of the consumer for the medication. Then, if the consumer's request has not been disqualified based on their answers to the questionnaire, a prescription is issued by a prescriber associated with the website. The issued prescription is then transmitted to a pharmacy associated with either the site and/or the prescriber. The concerns with this process are numerous.

There is no guarantee that the consumer has been truthful in completing the questionnaire. Likewise, there may be no quality oversight for the presciber; the pharmacist that completes the prescription; the pharmacy itself; or the product delivered to the consumer. If these drugs originate from a foreign country, there is a strong likelihood that the drugs themselves may not have been approved by the Food and Drug Administration (FDA). FDOH has investigated pharmacies that received over 300 prescriptions from a sole contracted physician in a single day—physicians that also see regular patients during the workday. Clearly, this is a serious issue.

FDOH Position

The position of FDOH and various licensure boards, including the Boards of Medicine, Osteopathic Medicine, Dentistry, Podiatry, and Nursing, is that prescribing based solely on an Internet questionnaire is below the standard of practice. Such a rule of the Board of Osteopathic Medicine has been challenged and upheld before a Florida administrative law judge. FDOH and the Board of Pharmacy believe that prescriptions issued in this manner are invalid. Pharmacies and pharmacists knowingly dispensing prescription drugs prescribed in this manner should be subject to discipline. Pharmacies or sites dispensing without a prescription are also in violation of state law.

The licensure boards are in the process of promulgating rules to specifically preclude these activities. In some cases disciplinary action has been taken based on existing statutes and rules with varying levels of success. FDOH Secretary Dr. John Agwunobi has created a Task Force of representatives of the various licensure boards to study areas where there may be synergies for collective board actions with respect to Internet prescriptions.

Dr. Agwunobi's recent letter to the Board of Pharmacy stated:

> "The Department of Health has been working on a strategy for addressing the Internet prescribing and dispensing issue. We are developing both an investigative team and a litigation team to deal with the disciplinary actions; and, we are coordinating our efforts with law enforcement at all levels, and across state lines. Since the Department also regulates wholesalers and distributors, we are working together on cases that involve these areas as well."

ILLICIT STOREFRONT PRESCRIPTION DRUG SERVICES

The second issue I would like to discuss is the use of unlicensed facilities—so-called storefronts that serve as middlemen for foreign prescription drug distribution. Foreign pharmacies are dispensing prescription drugs by mail to residents of Florida. Existing operations usually include Canadian pharmacies, but recent calls to our office indicate that a site or facility using Mexican pharmacies may also be involved.

Florida residents are drawn via advertising media to locations where prescriptions issued by licensed Florida prescribers are solicited and accepted for transmission to these foreign pharmacies. These "storefront" locations are not licensed as pharmacies and do not meet minimum requirements for licensure under their current method of operation.

A consumer with a licensed prescriber's prescription visits the storefront and provides the prescription and credit card information to the storefront operator. The prescription is then faxed to a Canadian physician who rewrites the original and then submits the new prescription to a Canadian pharmacy. The pharmacy prepares the drugs, which are then dispensed and mailed to the consumer's home in Florida. Similar to the concerns with Internet prescription filling, there are no guarantees that these drugs are FDA approved and there is no way to be certain of the drug's origin or history.

FDOH Position

The importation of prescription drugs in this manner is a violation of state and federal laws. Additionally, Florida Statutes (Section 465.0156) require licensure of non-resident pharmacies shipping prescription drugs to consumers in Florida. Florida law provides for the licensure of non-resident pharmacies licensed in another state, but does not reference foreign pharmacies. As a result, FDOH and the Board of Pharmacy have determined that the "storefronts" where prescriptions are solicited and accepted for dispensing by foreign pharmacies are engaged in the unlicensed practice of pharmacy.

In addition, Florida Administrative Code (Section 64B16-27.104 (2)) requires a pharmacy permit for locations maintained "from which to solicit, accept or dispense prescriptions." Florida Statutes (Sections 465.015 (3) and (4)) designate the unlicensed practice of pharmacy as a misdemeanor of the first degree.

Since unlicensed activity carries the potential for criminal sanctions, it is outside the jurisdiction of the department's Board of Pharmacy to investigate or prosecute. In cases where an investigation shows evidence of unlicensed activity, referral for criminal prosecution or civil action by the department will be considered. Closure of existing storefront operations will depend upon the results of those investigations.

We know that the cost of vital prescription drugs is more than a significant issue for many of our residents. FDOH shares their concerns with this issue. However, many, if not all, of the products ordered from foreign sources require a liability waiver prior to delivery. This particular system, while less expensive for the consumer, bypasses regulatory safeguards and places them at greater health risks.

Closing Statement

Again, this is a complex and evolving problem that crosses many jurisdictional boundaries with both national and international implications. I have addressed Florida's actions to date, but I think you will find similar safety concerns from my peers throughout the country.

FDOH is committed to addressing this safety issue and look forward to partnering with our federal counterparts to ensure continued safe and effective drugs for our residents. We are dedicated to ensuring secure access to prescription drugs, and applaud federal efforts along these lines. Undertaking an education campaign to explain the safety concerns associated with this practice, is a good first step in highlighting this issue for our residents, and to allow for informed decision-making.

We are also working within the state to study the extent of the problem, alternative solutions, enforcement options and legislative and regulatory actions, and look forward to sharing those lessons learned with other states, and the federal government.

Thank you for the opportunity to share Florida's experiences with you today on these important issues.

Mr. GREENWOOD. Well, thank you very much. The Chair recognizes himself for 10 minutes for questions. Let us walk through a hypothetical situation where a resident of Florida, first off, walks into a storefront, one of these storefront Canadian pharmacies that we have described in order to get a lower price product on a legitimate prescription from a legitimate local Florida doctor. First question I have is at what point, if at any point, does the senior citizen break State or Federal law in handing over a prescription to someone in that pharmacy and/or in making payment, receiving a drug knowingly from Canada? Has the senior citizen broken State or Federal law?

Mr. JOHN M. TAYLOR. I mean I will go first. Obviously, our focus isn't really on the senior.

Mr. GREENWOOD. I understand that.

Mr. JOHN M. TAYLOR. In that context——

Mr. GREENWOOD. And I am not suggesting you go and arrest them. I am just——

Mr. JOHN M. TAYLOR. Right. But in that context, at least based on the scenarios that I am familiar with, the senior has fulfilled—I mean they have met with their health care practitioner and have received, presumably, a valid prescription, which then facilitates

the rest of the conduct. So our focus is really on the—so just from a FDA standpoint, we don't see any liability there. I am not sure what the State——

Mr. GREENWOOD. Well, I am not asking you where you focus or if there is any liability, I am asking you is a law violated by the senior who takes a legitimate prescription from her physician, goes into a storefront and says, "I understand that if I give you this prescription, you can have—you will arrange to have this medicine shipped to my home from Canada at a less price—at a lower price than I can get at Costco," if that is the case. Is that a violation of State or Federal law?

Mr. JOHN M. TAYLOR. From a Federal standpoint, the answer is no.

Mr. JOHN D. TAYLOR. Mr. Chairman, I am not absolutely certain from a State standpoint. I am not aware of a State law that would be violated by the citizen, but obviously my understanding of the law deals with the pharmacists and pharmacies and so I am not sure.

Mr. GREENWOOD. Okay. Now, let us take the next actor here who is the fellow, the person behind the counter at that storefront, who takes that legitimate prescription and then faxes it or e-mails it to Canada and basically procures on this person's behalf a drug that would then be imported back from Canada. Has he or she broken a State or Federal law?

Mr. JOHN M. TAYLOR. Yes. Keeping in mind that some of these scenarios are fact-specific, we do believe that the owner of the pharmacy or the person who is facilitating the importation of products from Canada does indeed violate the act because of their acts to facilitate the illegal importation of these pharmaceutical products if indeed these products are not in compliance with the manufacturing, the storage, the labeling requirements that we deem are important and crucial to ensuring one's compliance.

Mr. GREENWOOD. And is that your understanding, sir, as well?

Mr. JOHN D. TAYLOR. Yes, sir. The Board of Pharmacy spent a great deal of time on this issue at a recent meeting, and the board's counsel, who is an assistant attorney general for the State of Florida, gave the opinion that this would be a violation; in fact, it would be the unlicensed practice. As I mentioned a couple of moments ago, there are three main elements here that can be a judge of that: Whether you solicit prescriptions, whether you accept prescriptions, and then dispensing. And all three of these elements essentially occur once someone walks into this unlicensed facility.

Mr. GREENWOOD. Okay. Now, let us walk through again what—and those are State laws or Federal laws?

Mr. JOHN D. TAYLOR. State laws.

Mr. GREENWOOD. State laws, okay. And you, sir, said that it is also a violation of Federal law.

Mr. JOHN M. TAYLOR. Correct.

Mr. GREENWOOD. Okay. Now, have either of your agencies prosecuted anyone in Florida or anywhere else, in the case of the FDA, for these violations of law?

Mr. JOHN M. TAYLOR. In the context of a storefront pharmacy, the answer is no.

Mr. GREENWOOD. And why is that?

Mr. JOHN M. TAYLOR. Well, quite frankly, at the time that we learned or became aware of the proliferation of these storefronts specifically here in Florida, we contacted the State of Florida and we have had negotiations with the very attorney that Mr. Taylor recognized. The reason we haven't done anything yet is it is still new to us, we are looking at the fact pattern. One of the important factors, Mr. Chairman, is the fact that FDA, for example, one of the charges that we would use is that this product is misbranded because it is dispensed, that it is not a valid prescription pursuant to State law.

During Mr. Taylor's testimony, he noted the fact that the State of Florida was proposing a rule that may be filed in a few months that articulates clearly that the use of an online questionnaire or the use or dispensing of a prescription without patient/physician interaction is not in accordance with State law. And if it is not in accordance with State law, then it automatically makes it a Federal charge that we can utilize. We are also, quite frankly, focusing on the Internet sites that many of these storefronts are utilizing across the board. So the bottom line is we are looking into the situation, but we have not taken any action as of today.

Mr. GREENWOOD. Anything to add to that?

Mr. JOHN D. TAYLOR. Just to say, Mr. Chairman, that complaints have been received, and they are under investigation.

Mr. GREENWOOD. Okay. If you went down to the Miami Airport, you would see, and I don't know if either of you have ever done that, but you would see truckloads, airplane cargo loads of cardboard boxes and other containers coming in with drugs, with postage stamps from places like the Bahamas, the United Kingdom, all over the place. And I am keenly aware of the limited resources, but I wonder to what extent the FDA, working with Customs, is saying, "We know that the flow is so gargantuan that is it's virtually impossible to stop it." But when you see particularly high volumes from a particular place, for instance, at the Miami Airport, as we sit here, there are probably a dozen garbage bags full of envelopes, manila envelopes containing Viagra, probably fake viagra, that has come in, much of it from one particular location in the Bahamas. Is the FDA at work with Customs to say, "We are going to turn all that stuff around and send it back or we are going to, it is not that much of a hop from here to the Bahamas, go in and find this location and shut it down"?

Mr. JOHN M. TAYLOR. Well, one of the positives that has occurred in the last year is that FDA strengthened its relationship with its international counterparts. One of the difficulties, aside from the resources, but just a logistical challenge, is working with our foreign counterparts not only to deal with a products at the point of origin but also obviously to deal with the product once it enters United States borders. And we have worked—we have had numerous discussions with the Canadian government. We are working with a couple States that are looking at the influx of products from India and Israel, two countries in particular who seem to be poised to augment the shortage of products that are—because the math doesn't add up and there is such proliferation of sites from Canada, it is obvious that not all these products could be coming from Canadian pharmacies, from the United States or from Canada itself.

And so there are other countries that seem poised to fill the gap by providing their product.

So we are working with the States, we are working with a larger number of foreign governments, we have gone to Geneva 2 years in a row to work with the Canadians—I mean, I am sorry, to work with our European counterparts and to meet with our Asian counterparts to do a better job of identifying the products at the time that they leave the foreign country so that we are able to more readily identify those products when they hit our shores.

One of the challenges is that there are so many packages unless we sort of have a heads up from a foreign country that these packages contain a specific drug, some of those packages can still evade our net.

Mr. GREENWOOD. Well, I understand all that, but what I just heard you say, in all due respect, is we are talking to these people, we are talking with those people, we are interacting with these people. What I haven't heard you say, we kicked down this door, we kicked down that door, we shut down this operation, we arrested people over here. Have there been——

Mr. JOHN M. TAYLOR. Sure. Let me walk you through some of the tangible cases. I mean we currently have several cases—actually several sites being investigated right now with several States, and those are specifically States that have taken a very tough position regarding what constitutes a valid prescription. And, obviously, that makes it easier for us to build a Federal case. But in the written testimony, for example, there is a case that we took where recognized that the product was actually coming in from Australia, and so we took action against the actual distributors here in the United States. There is another situation, which is really illustrative, of a case that is in the——

Mr. GREENWOOD. Can you let me interrupt you for a second?

Mr. JOHN M. TAYLOR. Sure.

Mr. GREENWOOD. What are some of the States that have taken such a hard line?

Mr. JOHN M. TAYLOR. The State of Arizona in particular has very strong and explicit language regarding what does not constitute a valid prescription. So you will notice we have a criminal case there. The State of Missouri traditionally has been very tough, the State of Texas, the State of Washington. So these are States where we have a tendency to build stronger Internet cases.

One case that is particularly illustrative is a criminal case that we brought in Nevada, and it involved a Germany company that essentially owned the German distributor and also owned the company that received the products from German. The company—the facility in Las Vegas not only imported the products but repackaged them and then facilitated the distribution in the United States. That is a situation where, again, we worked with our European counterparts to help understand the German operation, and then in light of the fact that they also had a United States operation, we criminally prosecuted them for conspiracy, for repackaging the products.

Mr. GREENWOOD. So people have gone to jail over this.

Mr. JOHN M. TAYLOR. Yes. We do have arrests in that case and several of these cases.

Mr. GREENWOOD. Okay. After this subcommittee had a hearing in June of 2001, nearly 2 years ago, the FDA proposed to the Department of Health and Human Services that it allow FDA and Customs to deny entry of all these illegal drugs into the U.S. and return them to the sender.

Mr. JOHN M. TAYLOR. That is correct.

Mr. GREENWOOD. What is the status of that proposed regulation?

Mr. JOHN M. TAYLOR. The status of the regulation is that the Secretary and the Commissioner are engaged in discussions regarding the proposal that we made 2 years ago.

Mr. GREENWOOD. I am sorry, say that again.

Mr. JOHN M. TAYLOR. I am sorry. The Secretary and Commissioner have been meeting regarding the proposal that we made 2 years ago.

Mr. GREENWOOD. Okay. What seems to be the holdup?

Mr. JOHN M. TAYLOR. Quite frankly, I am not sure. I know that they recognize that there are a complex number of issues here, but I think there is also recognition or a concern that using some of these short-term solutions, for example, the solution we proposed 2 years ago, really will not get to the crux of the issue, Mr. Chairman. I think the administration's feeling is that there is a need for a more comprehensive long-term solution, and they feel that that solution is Medicare prescription drug coverage. So it is something that is under active review. But as you know, over the last couple years there have been many thoughtful approaches, some put forth by the Hill, some put forth by FDA, and we have been unable to find one that addresses the safety and integrity concerns for the product, as well as providing some evidence that the costs of drugs would actually decrease. The Jeffords bill is an example where both Secretary Shalala and Secretary Thompson, as thoughtful as that was, it contained a requirement, a pedigree requirement that allowed the tracing of the product, a requirement that would have allowed for analytical testing as well as some other steps. But even in that context, we just could not certify that it was going to assure that the American public was going to be exposed to safe and effective products.

Mr. GREENWOOD. Well, I guess my own view is that the fact you can't solve the entire problem in one fell swoop shouldn't be an impediment to saying if we just took a significant size group of packages that are coming from another country and just sent them all back and did that even if it is a drop in the bucket, it begins to have an impact. People don't get what they are ordering, the company who is expecting to profit from this is finding all of this stuff back at its doorstep, and it just doesn't seem to me a lot of that is happening.

Let me finish with this question. In my opening, I mentioned Reverend and Mrs. Rode. Their son died of drugs he purchased over the Internet. The drugs came from South Africa. This committee knows the company and its location. We have shared that, I believe, with the FDA, and the question is what has the FDA done in this specific question for the Rodes and has OCI done anything at all?

Mr. JOHN M. TAYLOR. Before I answer that question, could I answer the question you posed before?

Mr. GREENWOOD. Sure.

Mr. JOHN M. TAYLOR. FDA still feels that that proposal is a good, viable proposal, the one we made in 2001, so I take your words to heart. We still think despite the fact that there might be a more comprehensive solution down the road, we still think that is a good proposal, and we look forward to having——

Mr. GREENWOOD. Well, when the 2-year anniversary occurs and nothing has happened, you can expect this committee to dance on the FDA's head.

Mr. JOHN M. TAYLOR. Fair enough.

Mr. GREENWOOD. The gentleman from Florida.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Mr. GREENWOOD. Oh, I am sorry.

Mr. JOHN M. TAYLOR. Yes. And let me answer the second one. I don't have the current status of the case but I remember, and OCI now reports to me at the time of that hearing they did not, but at the conclusion of that hearing they were told to go back and investigate that Internet site. My understanding is that they have done so. I will certainly get you a progress report.

Mr. GREENWOOD. Okay. We will expect then from you a full accounting of that——

Mr. JOHN M. TAYLOR. Fair enough.

Mr. GREENWOOD. [continuing] in letter form as soon as you can. Thank you.

The gentleman from Florida.

Mr. DEUTSCH. Thank you, Mr. Chairman. And, actually, not to be outdone of mothers who visit, my mom's actually in the audience. Mom, why don't you wave.

Mr. GREENWOOD. And a fine looking woman she is, Mr. Deutsch.

Mr. DEUTSCH. Thank you. Mr. Taylor—actually, let me—I want to take you, actually—this is an ad that appeared actually in this week's Broward Jewish Journal, and in fact this week's Broward Jewish Journal actually had seven ads for seven different locations of seven different Canadian pharmacies. It is not too hard to find them. And I guess the question is they are there. I mean tomorrow there are going to be more there. This one ad lists three different locations, I guess all of which are in Broward County. People are going, they are growing. I mean seven ads this week. Are they legal, are they not legal?

Mr. JOHN M. TAYLOR. Well, first of all, you are absolutely right. The number of sites are proliferating, and each week we see more and more. We think that the conduct—first of all, let me point out that the FDA approved—there are several things that strike me about that advertisement. One is, as I said in my oral testimony, despite the fact that many of these sites advertise that they are FDA-approved, we find that very hard to believe. In most cases, the products are not FDA-approved. And there are two reasons why we think that is the case. One is because under the Federal Food and Drug Cosmetic Act, the only party that legally can reimport a drug that is manufactured in the United States is the actual manufacturer. So for those products to be FDA approved and legal, they would have to be manufactured outside the United States in a FDA-approved facility, imported to Canada and then imported to

the United States, and we just don't see that type of widespread activity.

But going to your more global question, we think that ads like this facilitate illegal conduct, we think it facilitates the introduction of misbranded, adulterated and in some cases products that are dispensed without a valid prescription. So we do think that these ads facilitate—realizing that each of these fact patterns might have certain nuances, but we think that globally most of these fact patterns facilitate importation of products in violation of the act.

Mr. DEUTSCH. Do you have any idea how many of these pharmacies exist presently in the United States of America?

Mr. JOHN M. TAYLOR. No, we do not.

Mr. DEUTSCH. Are you aware if they exist anywhere outside of Florida at this point?

Mr. JOHN M. TAYLOR. Absolutely.

Mr. DEUTSCH. They do?

Mr. JOHN M. TAYLOR. Absolutely.

Mr. DEUTSCH. In a number of other States?

Mr. JOHN M. TAYLOR. Yes. Especially in addition to the State of Florida we are seeing them along the northern border, and one of the complaints that the northern border States have been making is that their own pharmacies are being harmed—the pharmacies along the northern border of the United States because many of their customers are using these Internet sites.

Mr. DEUTSCH. Has anyone from the FDA actually visited any of these locations?

Mr. JOHN M. TAYLOR. Any of the storefront locations?

Mr. DEUTSCH. That is correct.

Mr. JOHN M. TAYLOR. Not in the State of Florida. We have gone to a couple in the—I guess we went to one possibly in the State of New Jersey, but traditionally we have left it up to the States to visit the storefront pharmacy.

Mr. DEUTSCH. So are you aware—did the FDA visit one pharmacy of this type in New Jersey?

Mr. JOHN M. TAYLOR. I think we might have. I will have to double check on that. We have not been to any of the storefront sites.

Mr. DEUTSCH. So do we even know what these storefronts do?

Mr. JOHN M. TAYLOR. Yes, we do.

Mr. DEUTSCH. How do we know if we have never visited them?

Mr. JOHN M. TAYLOR. We know because we contact the States when we get word of these sites. We had a call at the beginning of February with 38 State Board of Pharmacies in the context of the storefront site that I guess in Delray Beach. After we saw that in the press, we called the State of Florida to learn generally how the operation was being conducted. We talked to the States about whether or not the site is operating in conformance with the practice of pharmacy. And then what the agency does is we focus on the Internet sites that are being utilized——

Mr. DEUTSCH. Let me just switch——

Mr. JOHN M. TAYLOR. Sure.

Mr. DEUTSCH. [continuing] to the other Mr. Taylor. I mean he has said it is your responsibility. Is it your responsibility?

Mr. JOHN D. TAYLOR. Well, we have received complaints of this type of thing, and those complaints are being investigated. Obviously they are confidential and so I don't know the details of those investigations, but I do know that they have been received and that the Secretary has asked the folks in his office to see what can be done. One of the problems——

Mr. DEUTSCH. Can I ask again this simple question: Are they legal or are they not legal?

Mr. JOHN D. TAYLOR. In the opinion of counsel for the Board of Pharmacy, no.

Mr. DEUTSCH. They are not legal.

Mr. JOHN D. TAYLOR. That is correct.

Mr. DEUTSCH. All right. So they are proliferating. This week there were seven advertisements at different locations; next week there could be 10. I mean if they are not legal, why are they existing? Have you visited them? I mean are you shutting them down? Do you plan to shut them down?

Mr. JOHN D. TAYLOR. They have been visited. One of the problems, without giving too much away of the strategy, in looking at this is one of the things that States that is is illegal is a Florida administrative code rule which doesn't have as much strength, obviously, as a statute. And so the folks that are pursuing this are being very careful that they do this right as they pursue it, sir.

Mr. DEUTSCH. Go ahead.

Mr. JOHN M. TAYLOR. Congressman Deutsch, I just want to clarify. I am not saying it is the States' responsibility. I am saying, actually, that the responsibility is complementary. It is the Federal Government and the States' responsibility. I noted that Mr. Lipscomb in the first panel said that he called FDA and FDA said it was the States' responsibility. In our relationships with the States, the States have the primary jurisdiction over the pharmacies, we often work sort of along these lines. The States will deal with the pharmacy issues, we will deal with the product issues. But it is——

Mr. DEUTSCH. Let me focus still on these pharmacies for a second. Why are they dangerous, in your opinion? I mean what is going on that is dangerous in these—why should we want to shut them down?

Mr. JOHN M. TAYLOR. I feel and FDA feels that they are dangerous because we do not know anything about the products that are being dispensed from these pharmacies. More specifically, we don't know how they are manufactured.

Mr. DEUTSCH. Let me ask you the question now. If you are ready to shut these down, are you ready to shut down Internet purchases from Canada, because how is this really different than the Internet purchases from Canada?

Mr. JOHN M. TAYLOR. It is indistinguishable.

Mr. DEUTSCH. So is the position of the FDA that you want to shut down Internet purchases from Canada?

Mr. JOHN M. TAYLOR. It is our position that the Internet sites from Canada are illegal and facilitating illegal conduct.

Mr. DEUTSCH. That is not the question I asked you. Is it the position of FDA that you want to shut down those sites?

Mr. JOHN M. TAYLOR. Yes. To the extent that we——

Mr. DEUTSCH. Yes.

Mr. JOHN M. TAYLOR. To the extent that we have researched this, we think it is important to take action against those sites.

Mr. DEUTSCH. Let me just follow-up which is just mind blowing to me at this point. How many scripts or how many packages of Internet purchases have been made for Canada in the last 12 months in the United States of America?

Mr. JOHN M. TAYLOR. Some of the estimates that we have received 3 to 4 million packages or more in the last 12 months.

Mr. DEUTSCH. Okay. In my office last week, who specifically came to us to present those numbers? The commissioner? Which commissioner? Commissioner McCullum was in our office last week. The number he used was 10 million. I mean where is the 3 million—was it 7 million less than last week?

Mr. JOHN M. TAYLOR. No. I mean the 10 million has been, quite frankly, one number; 3 or 4 million has been another number.

Mr. DEUTSCH. Maybe 100 million is another number, maybe 50 million is another number, maybe 250 million is another number.

Mr. JOHN M. TAYLOR. No. We cannot actually——

Mr. DEUTSCH. So the facts are you have no idea.

Mr. JOHN M. TAYLOR. Right. We cannot accurately quantify it.

Mr. DEUTSCH. You have no idea, really no idea.

Mr. JOHN M. TAYLOR. We cannot accurately quantify the number of packages that come into the United States.

Mr. DEUTSCH. You have absolutely no idea.

Mr. JOHN M. TAYLOR. To the extent we have any information it is anecdotal about the number.

Mr. DEUTSCH. And we are talking about millions, tens of millions.

Mr. JOHN M. TAYLOR. Absolutely.

Mr. DEUTSCH. And anecdotal.

Mr. JOHN M. TAYLOR. And increasing, increasing with each week.

Mr. DEUTSCH. I mean tens of million, potentially. Three million, 10 million. I mean we are not talking about thousands or hundreds.

Mr. JOHN M. TAYLOR. No, we are not; we are talking about millions of packages.

Mr. DEUTSCH. Millions of packages. And what you have testified now is that FDA wants to shut that down. I mean is that—I mean that is what I heard you say.

Mr. JOHN M. TAYLOR. Yes. FDA would like—absolutely. We would like to find a way to stem this tide and deal with this situation. One of the struggles, however, is having the resources to be able to check each package as it comes in and pursue the investigations that are necessary to deal with packages and lots of this size.

Mr. DEUTSCH. Let me just mention that our staff at the Miami facility, according to the officials there, said it takes about a half hour per package? FDA takes 2 hours per package. I mean, you know, we could basically get rid of the 5.8 percent unemployment in America tomorrow, we could hire everyone to go through the packages. They could probably speed it up a little bit. I mean, obviously, we are not going through 10 million packages a year. I mean it is just impossible.

Mr. JOHN M. TAYLOR. Well, correct, Congressman. I mean that is one of the reasons why we made the proposal 2 years ago is because it does take a long time to process each package, because when a package comes into the United States, pursuant to the act——

Mr. DEUTSCH. Right.

Mr. JOHN M. TAYLOR. [continuing] we need to provide notice. I mean there are due process requirements that we have to comply with, and so it takes an inordinate amount of time to process each package. So you are absolutely right.

Mr. DEUTSCH. Let me ask you a question. Is there any attempt by FDA, I mean there is an acknowledgement, I think, by you and the Commissioner that we really don't know what is going on. I mean there is no question, we have no real idea what is going on. Is there any systematic program in place at FDA trying to get our arms somewhat around what is going on?

Mr. JOHN M. TAYLOR. Congressman, we are actively discussing—if you note in the written testimony, a couple years ago we did what was called a Carson study, which is now dated, but at that time we did that study to get a better understanding of not only the quantity but more importantly the type of packages that were coming into the United States. Because what we learned from that pilot was that a lot of the products were not—I mean were antibiotics, pain killers, things that worked as well as other products that if they were not used properly were affirmatively dangerous.

But we think there is a better way or maybe a better approach to taking our knowledge base one step further. So we are actively looking at additional pilots that we think would help us understand better the problem we are dealing with. However, as you noted quite well, the scope issue is one that is readily apparently and hitting us in the face. It would just be a matter of getting more quantification about the pace and quite frankly the type of products that are coming here.

Mr. DEUTSCH. Let me kind of turn back a little. You are talking about what you are doing now and just brainstorming. I mean, obviously, our staff has been looking at this extensively as well, and one of the things I have asked the staff to look at is maybe think a little bit outside the box and basically say, okay, we have this phenomenon which is literally in the millions. Millions of people have availed themselves of this option. And I think the concern, truthfully, is that it really a two-tier system. I mean I think anyone who looks at it objectively understands that there is a certain amount of risk. We don't know how much that risk is, it is anecdotal at this point in time, but I don't think it is fair to say that there is no risk, I mean to go into one of these facilities. I would absolutely say that. And the FDA itself does an incredibly effective job in America in terms of the safety and efficacy of drugs in the United States.

Has anyone looked at, and I have asked from the FDA side, I have asked our staff to really try to think outside the box a little and basically say, okay, can we do something to deal with that risk from the Canadian side in particular? Because it does seem to, at this point, really be a Canadian phenomenon. It is not a Mexican phenomenon yet, it is not an Israeli phenomenon yet, although that

is the potential, and we have seen some indication that that is at the cutting edge, because I have actually seen ads now that people are now advertising you can better price through Israeli drugs or Mexican drugs, Bohemian drugs.

So have we looked at it to really say, okay, let us interact with our—or interface with our Canadian counterparts and try to have the efficacy and safety through the Canadian system that we can give the FDA seal of approval? Again, it is totally different than every way we are looking at it now, but maybe that is an approach as opposed to an approach which I think politically, honestly, you and I both know politically no one—the Secretary is not ordering the stopping of this importation at this point in time, I mean it is not happening. Congress is not legislating that it is going to stop happening. I mean this is the 800-pound elephant inside the tent, and maybe if we are not—I mean hopefully, I think all of our hope is that we are going to have a prescription drug benefit that we are going to pass in this Congress that is going to address this issue that tens of millions of people forcing themselves into effectively a second tier pharmaceutical system in America. If we can avoid that. I mean are you looking at all at that option?

Mr. JOHN M. TAYLOR. Yes. We have been working with the Canadians closely, and, quite frankly, we have not limited our options. The Commissioner met with the Deputy Minister of Health last month. We now have a—we had a meeting where industry, the Canadian government, the United States government met a couple weeks ago to look at the problem more globally and to look for some solutions. We are not—at this juncture, because of the breadth of the problem, we are not limiting ourself to any options or choices. We are looking at it all globally, including the question of whether or not there is some type of equivalency.

In addition, I am meeting with the Canadian officials next week to, again, continue discussions regarding this issue. We have shared with them web sites that are of concern to us, and we have talked to them about having actual contact points in the United States that can help them address these regulatory issues, not only in the context of these individual shipments but also in the context of looking at how this practice affects health care for the United States and Canada. So the equivalency that is something that has been put on the table as a possible idea.

Mr. DEUTSCH. Let me just follow up with two final questions. One is we just talked a little bit about this whole idea of Canada versus other countries.

Mr. JOHN M. TAYLOR. Right.

Mr. DEUTSCH. At the Miami facility, the staff going through these drugs noticed the drugs coming in from Mexico, the Bahamas, Central American countries, Europe and elsewhere. When seniors are ordering Internet drugs through Canada and they are working through one of these entities and they are sending faxes or Internet e-mail, what assurance do they have that they are actually coming from Canada?

Mr. JOHN M. TAYLOR. None at all, no assurance at all. And, quite frankly, as we begin to dig deeper, we are obviously finding tangible evidence that products indeed are not coming from Canada, they are coming from other countries.

Mr. DEUTSCH. The final question, which is really, I guess, related to this, and we have been looking. I mean we have met with pharmaceutical companies, our staff has been looking. At this point, we hear, and the chairman and others have mentioned, some anecdotal information of misuse. The truth is there is misuse of drugs absolutely correct, prescription drugs at the local pharmacy in south Florida. And I don't know if it is more, I don't know if it is less than purchase on the Internet. I mean there is misuse, there is drug interactions, people die really anecdotally all the time in terms of this type of thing.

The question really is what evidence do we have beyond almost what we have heard—I mean the U.S. Congress Oversight and Investigation Committee sitting here even though it is Florida this is the people. We should know. I mean we literally should know and you should know, and we have been looking. I mean maybe the problem isn't as bad, and that is really—this is an investigation here. Maybe the problem isn't as bad. What evidence do we have sort of what the adverse effects have been? I mean we can talk anecdotal, we can talk theoretically about the problems, but do we have any handle at all that maybe this is a good thing, maybe it is a system that is working, maybe tens of millions of Americans are living longer because they can afford the drugs, that they are not self-medicating and cutting their prescriptions in half and missing prescriptions. Maybe we should be encouraging, maybe the Federal Government ought to be offering the web sites.

I mean I am being very serious and sincere in what I am saying, because we are really—I think we are being open and honest in our investigation. What evidence do we have of there actually being a problem that is not anecdotal, that is not theoretical?

Mr. JOHN M. TAYLOR. Let me answer it in two parts. In regards to the adverse events, we get this question a lot. Our adverse event system does not discern between whether or not an adverse event is from a product that is purchased pursuant to an Internet site or not. So you are right, it is difficult to quantify. And as we know, adverse events occur whether it is purchased from a brick-and-mortar pharmacy or from an Internet pharmacy.

Mr. GREENWOOD. Would the gentleman yield for a second?

Mr. DEUTSCH. I would be happy to.

Mr. GREENWOOD. Let me just interrupt you there because that is a very important point. Why doesn't your system, your adverse event system, take that into consideration? I mean if you have a system for reporting adverse events, it would seem that in this day and age, given what we have been talking about today, that you would want to add a question to your adverse event investigation system that says where did it come from.

Mr. JOHN M. TAYLOR. Well, one of the Commissioner's five priorities is looking at our whole adverse event system, and it is one of the issues that is part of that discussion that we are going to take on. So you are absolutely right, Mr. Chairman.

Mr. GREENWOOD. Here is how long it would take me to do that. Good idea; yes, do it. Done.

Mr. JOHN M. TAYLOR. I agree. I agree.

Mr. GREENWOOD. Yield back.

Mr. DEUTSCH. Okay.

Mr. JOHN M. TAYLOR. So you are right. But one of the things we have done is we have talked at our State phone call about adverse events. We realized that the States through some of their poison control centers do have some evidence of adverse events that potentially resulted from products that they purchase over Internet sites. And we are getting that information from them and trying to quantify whether or not there indeed are tangible examples of people who have been harmed because of products purchased over the Internet.

The other part of my answer, though, is this: We see our job as trying to ensure that to the extent that adverse events can be mitigated, that this occurs. And part of that process is ensuring that products that have, quite frankly, not been manufactured properly do not make it here. I can give you some tangible examples of some products that we have noted as part of our Carson pilot or as part of some other investigations that we have done, and these are products that have what are called narrow therapeutic indexes.

I think the—I forgot, maybe, Mr. Chairman, it was you that raised the example of the Cardizem. Cardizem products that are used for seizures, products that are used for heart disease they have such a narrow therapeutic index, which means that if they are not manufactured exactly right or if the granule size of the active ingredient is not manufactured exactly right, then the health care of the person who is taking the product will be profoundly impacted. And we actually had a criminal case at FDA regarding a seizure product that was counterfeited overseas, and what happened is that the particulate—the granules, the particulate matter, was off just a little bit and what happened is that the product did not dissolve at the same rate in the blood and people who had never had—had no had epileptic seizures for 10 years began to have them. And I was one of the attorneys prosecuting that case, and that is, I think, a tangible example of where not knowing——

Mr. DEUTSCH. If I can just interject.

Mr. JOHN M. TAYLOR. Sure.

Mr. DEUTSCH. I mean I think we make a distinction, and this subcommittee has really spent a lot of time investigating, I mean there is a difference between the phenomenon of counterfeit drugs coming in and this phenomenon as well. I mean counterfeit drugs can still exist outside of Internet pharmacies, entering the country through wholesalers and that becomes a criminal enterprise, different than if there is a criminal enterprise versus this phenomenon. I think they can interrelate, but I don't think a counterfeit enterprise is proof of an adverse—I mean that counterfeit enterprise can still enter the United States without the Internet, and it probably did, because we have examples and extensive examples of counterfeited drugs entering the United States before there was any Internet pharmacies. Do you understand what I am saying?

Mr. JOHN M. TAYLOR. That is correct. I understand.

Mr. DEUTSCH. So counterfeit drugs does not equal Internet pharmacies.

Mr. JOHN M. TAYLOR. No, you are absolutely right, but the reason I use that example is because that example is illustrative of an actual situation where a product that was not manufactured in accordance with FDA statute and FDA regs led to actual harm.

Mr. DEUTSCH. Right. But let me ask you—again, I mean this is—wouldn't we see more injuries, I mean if this was an incredible abuse, 10 million minimum maybe, maybe more? I mean 10 million, wouldn't we see more stuff?

Mr. JOHN M. TAYLOR. It is difficult to say. I mean one of the things we have also learned in FDA, and this is in regard to adverse events, whether it be a drug or food, is that a lot of people don't even know that they are having an adverse event. If you are heavily medicated and you are taking different medications or, for example, in the context of food, you don't feel well, people often attribute to other factors other than the product that they took. So it is hard to tell.

Mr. DEUTSCH. Right. I know it is hard. If it was easy, we probably wouldn't be here. I mean how do we measure it? I mean what are we trying to do to measure it? Because one of the things out there, they are real people. I mean the first panel were real people who are literally making choices with their lives. Millions of American seniors are making choices with their lives today, okay? And I think one of the things we can do, if nothing else, is be helpful in providing some information to them about what the factors of that choice are. And you can do now, and we can do as well—I mean how do you measure what the problem is?

Mr. JOHN M. TAYLOR. Well, measuring the problem—aside from keeping track of the proliferation, measuring the problem is very difficult. What we have tried to do, and you just highlighted it a second ago, is we have tried to increase our consumer outreach and working with AARP and others and providing brochures that help people understand better, knowing that for some the choice, in light of the difference in costs, some are going to make the choice no matter what. But we have tried to—not only does FDA have a separate web site that instructs people how to purchase products online safely and gives some tips for doing so, we have also in the context specifically of foreign Internet sites put out brochures again trying to instruct people, trying to get people to interact with their health care practitioner before they purchase products over the Internet. And, in addition, the National Association Board of Pharmacy, their verified Internet practice sites, it is a seal, and that seal essentially indicates that the products that are purchased over that Internet site are manufactured in compliance with FDA and are in compliance with State law. So we try to encourage consumer awareness as one means of trying to alleviate the problem.

Mr. DEUTSCH. Thank you very much.

Mr. GREENWOOD. The Chair thanks the gentleman from Florida. The gentleman from New York is recognized for 10 minutes.

Mr. ENGEL. Thank you, Mr. Chairman. Listening to the testimony it just again hits me, something I said before and something we all know is, we are not doing what we should be doing in Washington. And because these things are happening, these Internet sites and also the franchises and other things that are happening, we have to now catch up to them, because it is a phenomenon that is relatively new.

Mr. Taylor of FDA—first of all, let me say that in hundreds and hundreds of hearings I have been to I have never been to one where both gentlemen have the same name. And then I noticed in

the next panel, Mr. Chairman, we have a Michael Jackson, so I think this is certainly a unique hearing. It was worth it coming to Florida for this.

Mr. Taylor from the FDA, you alluded in some of your answers to both Mr. Greenwood and Mr. Deutsch about resources for the FDA. I am wondering if you can expand on that funding. Obviously, this is something that is a fairly new phenomenon. Does the FDA feel that more funds are necessary from Congress to enable you to do what you have to do? Mr. Deutsch, I think pointed out, or was it Mr. Greenwood, about how—I think it was Mr. Greenwood, that there were two per hour, or whatever it is. Obviously, at that pace, there is no way we are going to be able to get to it. It was Mr. Deutsch because he talked about unemployment. But is funding a problem?

Mr. JOHN M. TAYLOR. Yes. We did receive some funding last year from Congress to hire additional investigators to work at our ports as part of the counterterrorism initiative. However, the proliferation of sites and the number of packages obviously has far eclipsed our ability to handle that. And the resource issues comes into play in two ways. One, pursuant to the act, as I noted before, when a package comes in, we need to provide notice to the consignee that their package has been seized, and then they have an opportunity to challenge the seizure. That in and of itself is time consuming, so that is one aspect of it. But the other resource aspect of it is that quite frankly we just do not have enough people at this time to cover all the ports. And so at some ports we will have people there Monday, Tuesday and Wednesday, and then the next 2 days of the week they will go to another port, so our coverage is incomplete. That is the two ways.

Mr. ENGEL. Could we really—since this problem is obviously tremendous and getting deeper or worse by the day, can we ever really have enough resources? I mean wouldn't it take literally to be at every port and to cover it the way we need to cover it, I mean wouldn't you have to put on tens of thousands of additional employees? So, therefore, since that is obviously not feasible, what can be done with the resources we have to at least make a dent in this? Obviously, we are not making a dent in it now.

Mr. JOHN M. TAYLOR. Sure. You are absolutely right. Additional resources would help us stem the flow somewhat, but, obviously, the number of resources that are required to stop this I can't even begin to quantify them. I am not sure there is actually a figure that would allow us to look at every single package that is coming into the United States. So instead what we have tried to do is, first of all, we have tried to emphasize the use of various tools that allow the public to understand some of the concerns that we have when one uses one of these sites to purchase their products. We have, as I said before, drafted several brochures that we have issued that we have actually given to storefront pharmacies to help people understand not only the risk but also to help them understand some of the factors that they should engage in when they are making a decision whether or not to purchase products over these sites. We also have worked with the States and, as I said before, increasing our working relationship with many of our foreign coun-

terparts to do the best we can to leverage the limited resources that we have to address this problem.

Mr. ENGEL. In working with the States, Mr. Taylor of Florida, have you worked with other States, have you put your heads together and tried to talk about things that may have come up or is each State sort of on its own?

Mr. JOHN D. TAYLOR. Well, the National Association of Boards of Pharmacy obviously has helped in that regard. And we were on the 38-State teleconference that Mr. Taylor mentioned earlier, which was a time for interaction between the States as well. But it has been fairly limited, I think.

Mr. ENGEL. Okay. Mr. Taylor of the FDA, I am told that the committee staff have just visited the Miami International Mail facility to examine what kind of drugs are coming to the United States. Have you been to that facility?

Mr. JOHN M. TAYLOR. No, I have not. I have not been there since this proliferation of mail. I have been to the Miami facility about 5 years ago, but obviously the conditions today are much different than they were then.

Mr. ENGEL. Well, we are told that FDA and U.S. Customs staff are virtually swimming in thousands of shipments of controlled substances and counterfeit drugs and others, and some might be legitimate and some not. Are you aware that they are literally swimming in thousands of shipments?

Mr. JOHN M. TAYLOR. Yes, I am.

Mr. ENGEL. And while some of these shipments are legitimate, obviously many are highly suspect?

Mr. JOHN M. TAYLOR. That is correct.

Mr. ENGEL. You mentioned about the two inspector hours to process a single shipment through the Oasis System. Are we increasing those numbers of inspectors above two?

Mr. JOHN M. TAYLOR. Quite frankly, I couldn't answer today as to what our staffing plans are for the Miami facility. However, as I said earlier, in light of last year's funding request, we were able to hire additional investigators to work at the ports, and we have increased our port coverage across the United States. One of our priorities has been boosting the level of—or boosting the number of people, for example, in our UPS hub in Louisville, because, as large as—or as steep as the increase is in the context of the mail, it is even steeper in the context of UPS. So we have been focusing on increasing our staffing at Federal Express and UPS, and to the extent that we can bring more people into Miami, it is something I am certainly willing to look into.

Mr. ENGEL. In order to deal with this, do we really need to change the laws to deal with this? Is that correct?

Mr. JOHN M. TAYLOR. Well, in order to finalize the proposal that the chairman was referring to, the proposal—specifically, the proposal that would allow us to send the packages back or to unilaterally destroy them, we would need a statutory change, because, as I said before, as of right now, we cannot send the packages back or destroy them; we have to provide some notice to the recipient that the package has been detained by FDA and give them an opportunity to respond. So, yes, it would require a legislative change, specifically to section 801 of the act.

Mr. ENGEL. Let me ask Mr. Taylor of Florida, is it true that these walk-in pharmacies—we are told that these walk-in pharmacies may soon be showing up here in Florida malls, in kiosk operations. Have they been? Have you heard that they will be? Is that something that the State of Florida has learned about?

Mr. JOHN D. TAYLOR. I have heard about that type of situation. I think that many of the first facilities often were insurance company offices and things like that, but I have heard that there could be plans for offices in malls as well, sir.

Mr. ENGEL. Do we know anything about the operators of these walk-in pharmacies? Are any of them trained in the practice of pharmacy?

Mr. JOHN D. TAYLOR. I would expect that they are completely not. They are certainly not licensed pharmacies or pharmacists at the facility, sir.

Mr. ENGEL. The other Mr. Taylor, do we know anything about the operators?

Mr. JOHN M. TAYLOR. Of the storefront pharmacies?

Mr. ENGEL. Yes.

Mr. JOHN M. TAYLOR. Yes. I mean we feel that we have a good understanding of how they work based on our discussions with the State of Florida and the other States who house these pharmacies.

Mr. ENGEL. I want to ask Mr. Taylor, Federal, about Glaxo. They are, as you know, embarking on a policy not to export to Canadian wholesalers if these Canadian wholesalers send their drugs to the United States. Does the FDA support that move by Glaxo, and, if so, why?

Mr. JOHN M. TAYLOR. Without limiting it to Glaxo, we, quite frankly, are supportive of any steps to ensure that the act is being complied with.

Mr. ENGEL. Doesn't this, though, if Glaxo feels that it has got to take matters into its own hands, does it show that the FDA is not doing what it should be doing if Glaxo is trying to do it this way?

Mr. JOHN M. TAYLOR. Sir, I don't know. I guess you would have to ask Glaxo. I mean, obviously, it is indicative of the fact that there appears to be such a flow of product from Canada that others are looking at alternatives to the current system.

Mr. ENGEL. So what we are saying, in essence, is that these pharmacies are not regulated at all. I mean there is really—it is just an impossibility to regulate them.

Mr. JOHN M. TAYLOR. I guess I would phrase it differently. I believe that they are subject to both State and Federal law, or at least some State laws and certainly Federal law. I think the challenge comes in doing the investigatory work and taking the law enforcement steps that are necessary to completely shut off the supply of these products or even stem the supply of products to a point where we feel comfortable that the American public can be guaranteed that the products that they receive once they order from these sites are products that are safe and effective, in compliance with Federal law and are safe from a public health standpoint.

Mr. ENGEL. Thank you. Let me ask the other Mr. Taylor, I have two final questions. We have here—we have received a copy of the recent report issued by the Florida Grand Jury on drug diversion and the State's drug counterfeit problems. This seems to be an in-

creasingly serious problem here in Florida, probably in other States as well, but certainly in Florida, obviously many senior citizens, would you agree?

Mr. JOHN D. TAYLOR. The grand jury report that dealt with counterfeit drugs and diversion through wholesaling?

Mr. ENGEL. Yes.

Mr. JOHN D. TAYLOR. Okay. Well, I have only been in that office 2 weeks, but certainly in talking to my colleagues it is seen as a very serious issue; yes, sir.

Mr. ENGEL. Well, in this report, it is described that a number of wholesalers here in Florida are now dealing in counterfeit drugs, perhaps with their knowledge, without their knowledge, we really don't know. Are these drugs coming from Internet operations? If not, where? And what are the theories that you have about where these drugs might be coming from?

Mr. JOHN D. TAYLOR. I am not confident to answer that question today. I certainly could try to get that information for you, but I haven't been in that office long enough to be competent in that area, sir.

Mr. ENGEL. Okay. Thank you both, gentlemen. Mr. Chairman, thank you.

Mr. GREENWOOD. The Chair thanks the gentleman and we thank Messieurs Taylor for being with us very much. Thank you for your testimony. You are excused, and we will take a brief break while we bring on the next panel. Thank you, gentlemen.

[Brief recess.]

Mr. GREENWOOD. Okay. We welcome our third and final panel. We thank you, gentlemen. We have with us Dr. Elliott Hahn, who is the chairman and president of Andrx Corporation; Mr. Michael Jackson, the executive vice president of Florida Pharmacy Association in Tallahassee; Mr. Carl A. Ruiz, who is the pharmacy director for Navarro Discount Pharmacies in Miami; and Mr. Robert N. McEwan, who is the CEO of MEDBANK of Maryland in Towson, Maryland. Gentlemen, thank you all for being with us.

You probably heard me say to the other witnesses in the other panels that this is an investigative hearing and it is our practice to take testimony under oath at these hearings. Do any of you have objections to giving your testimony under oath? Okay. Seeing no such objection, I should advise you that you are entitled to be represented by counsel at this hearing. Do any of you wish to be represented by counsel? Okay. In that case, if you would each stand and raise your right hand.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are under oath, and we look forward to your testimony. We ask you to try to hold your testimony to about 5 minutes. We have about 45 minutes left for the entire hearing, and we want to spend as much time as possible with questions. We are going to start with Dr. Hahn.

TESTIMONY OF ELLIOTT HAHN, CHAIRMAN AND PRESIDENT, ANDRX CORPORATION; MICHAEL A. JACKSON, EXECUTIVE VICE PRESIDENT, FLORIDA PHARMACY ASSOCIATION; CARLOS A. RUIZ, PHARMACY DIRECTOR, NAVARRO DISCOUNT PHARMACIES; AND ROBERT N. McEWAN, CEO, MEDBANK OF MARYLAND, INC.

Mr. HAHN. Thank you, Mr. Chairman, for the introduction and especially for the invitation to give testimony today on the important issue of access to pharmaceuticals that are affordable and specifically prescription drugs. A key indicator of the seriousness of this problem is the alarming number of senior citizens who are purchasing their medications illegally over the internet.

As a member of the pharmaceutical industry, Andrx strongly opposes the unauthorized sale or distribution of products procured via the Internet. Seniors on fixed incomes, as well as the millions of others that are uninsured or under insured Americans who purchase their prescription drugs illegally over the Internet, cannot be certain of the purity of their medications or the accuracy of the dosage. In addition, they might be subject to potentially harmful drug-drug interactions without the intervention of a licensed pharmacist who has a complete patient history. Furthermore, patients' privacy can be at risk when purchasing drugs on the web. But the dramatic rise in Internet importation is not the underlying problem. It is only a reaction to the real issue of access to affordable medication for those who lack or have limited prescription drug coverage.

The importance of this issue is underscored by the number of Americans having to pay the full freight for expensive pharmaceuticals. This number is rising rapidly and dramatically. The uninsured in this country already exceeds 41 million people and is growing. In the coming year, every 2 hours or roughly the length of time that we are sitting in this room, another 465 Americans will lose their health insurance. Add to that the millions of Americans who are under insured and the scope of the problem becomes clear.

Andrx recognizes our responsibility as a member of the health provider community to provide affordable medications for uninsured or under insured patients. At Andrx, our mission is to provide safe and efficacious pharmaceuticals at prices that everyone can afford, including seniors, the uninsured and the under insured.

Since its inception, Andrx has been involved with developing generic versions of difficult to replicate blockbuster drugs or brand name products. The pharmaceuticals products that we prepare are those at cost-effective prices. Recently, we have leveraged our technology base to develop what we refer to as value-branded products, and the first one is a cholesterol fighter called Altocor.

Altocor is a highly effective extended-release version of the first statin, known as lovastatin, which was introduced 16 years ago and has been used safely ever since. Altocor employs patented technology developed by Andrx to reduce LDL, or the bad cholesterol, by as much as 41 percent. And what is more, Altocor is the most affordable option among currently promoted statins for the millions of Americans who are at risk for cardiovascular disease.

Altocor's high level of efficacy and safety, combined with its value pricing, makes it a prime example of industry innovation. A meas-

ure of its success is shown by the fact that Altocor is already covered by almost all State Medicaid programs and is on the Medicaid preferred drug list in a number of States that have implemented managed-care like formularies.

In April, Andrx will implement a new program designed to meet the needs of those who lack or who have limited prescription drug coverage. This initiative is called the SAVE Program. There is no enrollment or paperwork required for the program; instead patients simply receive a SAVE card and an Altocor prescription from their doctor and present the card when they pay for their Altocor prescriptions. Unlike other pharmacy card programs, access to the SAVE program is not limited by a patient's age or their income. Andrx is very excited about the SAVE Program. We believe it will help thousands of patients who lack or have limited prescription drug coverage by offering access to a highly effective drug in one of the most important therapeutic categories.

But that's not all. Andrx is readying a pipeline of other products that will adopt the same approach. These products will be designed to treat widespread illnesses effectively, safely and affordably. That, in fact, will be the hallmark of the Andrx product line. And, as I said earlier, we can see this as a new form of innovation that can serve as a model for the pharmaceutical industry as a whole.

The pharmaceutical industry continues to make great strides in applying innovative therapeutic technologies to new drug development, but if it is to rise to the challenges of our times, the industry must also use its resources to create drugs that couple efficacy and safety with value. I thank you.

[The prepared statement of Elliott Hahn follows:]

PREPARED STATEMENT OF ELLIOT HAHN, CHAIRMAN AND PRESIDENT, ANDRX CORPORATION

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The pharmaceutical industry continues to make great strides in applying innovative therapeutic technologies to new drug development. But if it is to rise to the challenges of our times, the industry must also use its resources to create drugs that couple efficacy and safety with value.

Thank you.

Mr. GREENWOOD. Thank you.

And let us next turn to Mr. Jackson.

TESTIMONY OF MICHAEL A. JACKSON

Mr. JACKSON. Thank you, Mr. Chairman, members of the committee. I thank you for allowing me the opportunity to present to you today. I am Michael Jackson, I am executive vice president of the Florida Pharmacy Association.

A business industry is being developed here in Florida that has no governmental oversight. This industry is inserting itself into the professional practice of pharmacy by serving as a drop-off point for prescriptions. The Florida Pharmacy Association has learned through its members and in the media that these storefront centers are opening for business with the intent on accepting prescriptions written by licensed prescribers. These prescriptions are then transmitted to a foreign source for processing and shipping directly to Florida residents. As a pharmacist, I see this as a significant public health and safety risk. Patients who seek pharmacy services in this manner are presenting themselves to untrained, unqualified and unlicensed individuals.

Not all prescriptions needed by patients are available through foreign sources. In those cases, we see patients will have to seek services from their local pharmacy provider. It is not uncommon for patients to forget to disclose to their health care provider all of the prescription medications that they are taking. Knowing that many of these drugs are obtained through questionable sources there is a tendency to withhold critical medical information from the phar-

macist. The dispensing pharmacist may be unable to recognize why dispensed medications are not working or, worse, may be unable to detect a possible life threatening drug interaction. The consumer could be subject to increased health risks resulting in illness, inability to work, impairment or a possible hospital admission. This business industry is not only unregulated but could be in violation of State law as evidenced in Florida Statutes 465.003, paren 13 and 465.015.

There is an economic impact of the foreign alternative solution. Allowing the continued importation of prescription drugs from foreign countries places Florida pharmacy providers at an unfair disadvantage. Florida pharmacies are clearly unable to purchase prescription drugs at the prices listed in the media ads for foreign outlets. Many of you often receive mail from constituents asking the simple question, why do my drugs costs so much? I cannot explain why prescription drugs are available at such reduced prices from other countries. The committee needs to know that 80 percent of the cost of the average domestic retail prescription price represents costs to the pharmacy over which we have absolutely no control. The remaining 20 percent of the prescription price represents operating costs, such as heat, light, rent, salaries, computers, professional counseling and other overhead expenses.

Florida pharmacies pay in excess of $1.3 billion in taxes to the State of Florida and perhaps a significant amount to the Federal Government in taxes and fees. Many of our members are reporting a flattening of their business that can only be explained by suggesting a relationship between these unlicensed business entities serving foreign mail order facilities and a decline in patient encounters. We are concerned that if this trend continues then our State's pharmacy providers will have no choice but to begin limiting services or laying off staff. Staff reductions is not something that our economy can withstand during these difficult times. State and Federal budgets can ill afford to be faced with having to service the unemployed.

There is evidence that consumers who choose to obtain medications from foreign sources could be waiving their rights to seek relief from bad health care providers or ineffective drugs. Many of the waivers signed by patients are very long and written in very fine print. Some of the worst, and most common, terms include requiring patients to agree to waive all damages for any reason, no liability if the drugs cause patient harm, no liability if the drugs seized at the border, no returns or refunds—ever, that the patient is seeking alternative advice from a physician and is not relying on the importer for health care consultations, waiving privacy and allowing the company to use patient health information, relieves the company of any duty to ask questions about patient's health, including other drugs being taken or other drug utilization review issues, gives company open-ended power of attorney to act on patient's behalf, that any claims against company must be filed only in the foreign country, and patient waives application of U.S. law, allow generic substitution at the company's choice, that drugs will not be delivered in child-protective packages, will waive all warranties about quality, legality, et cetera.

Consumers, particularly our elderly here in Florida, may be making choices without understanding that they could be giving up significant rights in the event that something may go wrong. They would have nowhere to go and no one to turn to.

There is no system in place that assures that product from foreign sources are manufactured, stored or shipped properly. Prescriptions shipped to Florida residents may be subject to extreme heat or cold. These temperature extremes may result in an ineffective or unusable product. The Food and Drug Administration has strict guidelines on the manufacturing of prescription drugs here in the United States. Pharmacists have come to rely on the integrity of the product that they purchase. There is evidence even within our own safety system of counterfeit or adulterated product finding their way into the domestic drug distribution system.

Florida plans to implement programs that are designed to get tighter controls on drug product. Unfortunately, such programs will do little to slow the flow of possibly tainted drugs crossing our State line from foreign sources. At risk are our citizens taking life-maintaining prescription drugs that may or may not work. Patients taking ineffective prescription medication may find their conditions worsening and return to see their physician. Physicians might make a medical decision to increase a patient's dosage to dangerous levels thinking that the patient is not responding when it was the product that was not working. There is something that our society could not realize that something was wrong until after a catastrophic medical event were to occur. With so much discussion on homeland security could there be some risk to our citizens from prescription medications process through foreign sources and arriving here in Florida?

In summary, pharmacists across Florida clearly understand the problems faced when citizens struggle to find ways to obtain their prescription medication. In a number of cases, these health care providers can work with patients to help them to find more cost-effective choices by working with their physicians. Studies have shown that the services provided by pharmacists significantly help to lower total health care costs and reduce hospitalizations. There are a number of suggested proposals that Congress could consider to assist the uninsured obtain pharmacy services here in the United States without having to rely on unlicensed activity.

I would like to thank again the members for allowing me the opportunity to present today.

[The prepared statement of Michael A. Jackson follows:]

PREPARED STATEMENT OF MICHAEL A. JACKSON, EXECUTIVE VICE PRESIDENT, FLORIDA PHARMACY ASSOCIATION

UNEGULATED HEALTH CAE ACTIVITIES COULD COMPROMISE PATIENT SAFETY

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Not all prescriptions needed by patients are available through foreign sources. In those cases patients will have to seek services from their local pharmacy provider. It is not uncommon for patients to forget to disclose to their health care provider all of the prescriptions that they are taking. Knowing that many of these drugs are obtained through questionable sources there is a tendency to withhold critical medical information from the pharmacist. The dispensing pharmacist may be unable to recognize why dispensed medications are not working or worse may be unable to detect a possible life threatening drug interaction. The consumer could be subject to increased health risks resulting in illness, inability to work, impairment or a possible hospital admission.

This business industry is not only unregulated but could be in violation of state law as evidenced in Florida Statutes 465.003 (13) and 465.015.

ECONOMIC IMPACT OF THE FOREIGN ALTERNATIVE SOLUTION

Allowing the continued importation of prescription drugs from foreign countries places Florida pharmacy providers at an unfair disadvantage. Florida pharmacies are clearly unable to purchase prescription drugs at the prices listed in media ads for foreign outlets. Many of you often receive mail from constituents asking the simple question: "Why do my drugs costs so much? I cannot explain why prescription drugs are available at such a reduced price from other countries. The committee needs to know that 80 percent of the cost of the average domestic retail prescription price represents costs to the pharmacy over which we have absolutely no control. The remaining 20% of the prescription price represents operating costs, such as heat, light, rent, salaries, computers, professional counseling and other overhead expenses.

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CONSUMERS COULD BE SIGNING AWAY THEIR RIGHTS

There is evidence that consumers who choose to obtain medications from foreign sources could be waiving their rights to seek relief from bad health care providers or ineffective drugs. Many of the waivers signed by patients are very long and written in very fine print. Some of the worst (and most common) terms include requiring patients to agree to:

- Waive all damages for any reason
- No liability if the drugs cause patient harm
- No liability if the drugs seized at the border
- No returns or refunds, ever
- That the patient is seeking alternative advice from a physician and is not relying on the importer for health care consultations
- Waive privacy—allow company to use patient health information
- Relieves company of any duty to ask questions about patient's health (e.g., other drugs being taken or other DUR)
- Gives company open-ended power of attorney to act on patient's behalf
- That any claims against company must be filed only in the foreign country, and patient waives application of US law.
- Allow generic substitution at the company's choice
- That drugs will not be delivered in child-protective packages
- Waive all warranties about quality, legality, etc.

Consumers particularly our elderly here in Florida may be making choices without understanding that they could be giving up significant rights in the event that something may go wrong. They would have nowhere to go and no one to turn to.

COUNTERFEIT PRODUCT COULD FIND THEIR WAY INTO FLORIDA'S HEALTH CARE SYSTEM

There is no system in place that assures that product from foreign sources are manufactured, stored or shipped properly. Prescriptions shipped to Florida residents may be subject to extreme heat or cold. These temperature extremes may result in an ineffective or unusable product.

The Food and Drug Administration has strict guidelines on the manufacturing of prescription drugs here in the United States. Pharmacists have come to rely on the integrity of the product that they purchase. There is evidence even within our own safety system of counterfeit or adulterated product finding their way into the domestic drug distribution system. Florida plans to implement programs that are designed to get tighter controls on drug product. Unfortunately such programs will do little to slow the flow of possibly tainted drugs crossing our state line from foreign sources. At risk are our citizens taking life maintaining prescription drugs that may or may not work. Patients taking ineffective prescription medication may find their conditions worsening and return to see their physician. Physicians might make a medical decision to increase a patient's dosage to dangerous levels thinking that the patient is not responding when it was the product that was not working. This is something that our society could not realize that something was wrong until after a catastrophic medical event was to occur.

With so much discussion on homeland security could there be some risk to our citizens from prescription medications process through foreign sources arriving here in Florida?

SUMMARY

Pharmacists across Florida understand the problems faced when citizens struggle to find ways to afford their prescription medication. In a number of cases these health care providers can work with patients to help them to find more cost effect choices by working with their physicians. Studies have shown that the services provided by pharmacists significantly help to lower total health care costs and reduce hospitalizations. There are a number of suggested proposals that congress could consider to assist the uninsured obtain pharmacy services here in the United States without having to rely on unlicensed activity.

Mr. GREENWOOD. I thank you very much, sir, for your testimony. Mr. Ruiz.

TESTIMONY OF CARLOS A. RUIZ

Mr. RUIZ. Mr. Chairman and members of the subcommittee, let me welcome you to Miami. I am Carlos A. Ruiz, director of Pharmacy for Navarro Discount Pharmacies based here in Miami. We operate 16 pharmacies throughout the Miami-Dade and Broward County areas. Last year, we filled over 1.7 million prescriptions and employed over 1,300 Floridians. We very much appreciate you holding this hearing on issues relating to imported prescription pharmaceuticals. In my statement today, I want to talk about the importance of patients having access to the local pharmacy and why reimportation can be dangerous for consumers. I also want to talk about programs that already exist in this country that help seniors with their medication purchases that do not require them to look across the border for help.

When a patient arrives at their local community pharmacy, be it a chain pharmacy or an independent, they come into contact with one of the most accessible and trusted providers in the entire health care system. It is estimated that 95 percent of Americans live within 5 miles of a retail community pharmacy. For almost 20 years, surveys show that pharmacists are among the most trusted health care professionals. Thus, the vast majority of Americans are never far from a highly trained health professional who can provide medications or advice on a wide range of health care issues. Convenient access to community pharmacies makes us a critical part of society's health care safety net.

Prescription medications are the most widely used and cost-effective health care interventions used by patients today. Modern prescription drugs have extended and improved the lives of millions of Americans and saved millions of dollars through shortened length

of illnesses, increased productivity and reductions in hospitalization and medical procedures. Community pharmacy is proud of the role we have in assuring the safe and effective use of these therapies.

Every day, our pharmacists see seniors struggling to afford their prescription medications. We get many questions from seniors about how they can buy their drugs from Canada and other countries where prescription drugs might be less expensive. It is true that the prices for drugs in Canada and other countries are less expensive than those in the United States. The comparisons are inevitable. We have also seen a drop off in business in some of our pharmacies because of the growing illegal reimportation trade going on, especially in the State of Florida where there is a large senior population. However, we discourage seniors from obtaining their drugs through these methods, because the drugs they receive might be counterfeit, of impure quality or simply not the drugs that they are supposed to be.

Moreover, foreign-imported drugs do not have the important safety and quality checks that are built into the current U.S. community pharmacy-based distribution system. Seniors also do not receive face-to-face counseling or medication management from pharmacists by purchasing drugs from these international schemes, potentially jeopardizing their life and health.

There are other legitimate ways for seniors to obtain medications without having to subject themselves to these potential safety and quality problems, and I am here today to discuss these approaches. I can offer many anecdotes to the committee of patients that come into our pharmacies who cannot afford their medications. Some of these stories are heartbreaking. What can pharmacies do to help these seniors obtain their prescription drugs?

First of all, our pharmacists work with patients and their doctors to try to maximize the use of lower-cost generics when they are available on the market. The savings from using generics are unmistakable. At Navarro, the average brand name prescription is about $65, while the average generic prescription is $16. That is a difference of close to 400 percent. Obviously, if a generic substitute is not available, we will try and work with the doctor to see if the patient can, in fact, take a generic version of another drug or a less expensive therapeutically equivalent branded drug.

With billions of dollars in brand name drugs coming off patent over the next few years, we believe that it is critical that seniors have incentives to use generics. We will also try to help patients use a less expensive over the counter medication if they cannot afford their prescription drugs. These OTC medications may not work as well as the prescription versions, but the choice for patients sometimes comes down to taking that—it comes down to taking something that may not work as well or not taking anything at all.

Second, many of Navarro's pharmacies also offer discounts to senior citizens on their prescription drug purchases. Navarro is a deep discount pharmacy. Most pharmacies in general offer discounts of about 10 percent, but each pharmacy has its own policy on discounting their prices to seniors. Some pharmacies have their own arrangements with other groups and entities to offer prescrip-

tion discounts. For example, we work with a group called Liga Contra el Cancer to offer prescription discounts to cancer patients who cannot afford their medications. We also work with church organizations, such as St. Vincent de Paul, to assist them in providing low-income or indigent patients with needed medications they cannot buy.

Consumers already reap the benefits of the highly competitive retail pharmacy marketplace. We are a fiercely competitive industry, as evidenced by our 2 percent net profit margins. If you do not like the price at one pharmacy, you can go to another. Many pharmacies will match their competitors' prices. And, yes, retail pharmacy prices do vary store to store, reflecting differences in the cost of doing business, loss leaders, and other factors. The fact is consumers can and should shop around for the most favorable prices for their prescriptions. You should know that pharmacies do not have much, if any, margin on prescription drug business. Yes, costs of drugs are high, but that is primarily due to the high costs of buying prescription drug products from the manufacturers.

Third, we can help the poorest seniors access the Patient Assistance Programs that pharmaceutical manufacturers have established. Clearly, these programs provide a short-term benefit to some low-income seniors, but they are not an adequate solution or appropriate substitute for meaningful, long-term prescription drug coverage. Almost all pharmaceutical manufacturers have established assistance programs that provide free prescription drugs to patients, including senior citizens, who do not have the resources to obtain their medications.

These programs usually require that the patients' physicians certify to the manufacturer that the patient does not have the resources to obtain their prescriptions. Many low-income seniors forgo their medications because they do not have the resources to purchase them but remain unaware that such programs exist. The Pharmaceutical Research and Manufacturers Association, also known as PhRMA, has a web site describing these manufacturer-based programs, which can be found at www.phrma.org. Eligibility standards and benefits vary among manufacturers. Also, the complex enrollment forms can make accessing these programs challenging. Several States, however, recognizing the positive impact that these programs might have on helping seniors obtain prescriptions, have taken action to educate them about these programs and simplify the enrollment process.

A relatively new program, called Together Rx, offers significant discounts to low-income seniors on the purchase of their medications. Under this program, manufacturers and pharmacies have joined forces to offer seniors discounts of up to 40 percent on almost 150 popular brand name prescription medications. At Navarro, we have gone a step further and offer discounts on generic medications as well. These prices are as good in many cases as the prices that seniors would pay for drugs from Canadian sources. These discounts are passed along to seniors at the pharmacy counter at the time of purchase. Over half a million seniors have enrolled in the Together Rx program since its inception, saving $3.2 million for seniors each week, or about $32 million to date.

Other manufacturers have developed programs for low-income seniors that only require that they pay a flat fee for their prescription drugs. For example, under the Lilly Answers program, low-income seniors only pay $15 for a 30-day supply of most of the Lilly outpatient brand name drugs. Pfizer has a similar program, charging $12 for a 1-month supply of many of their outpatient medications. Seniors can find more information by clicking on www.togetherrx.com. Navarro participates in this program, and we view this as a model for a potential Medicare drug benefit for seniors.

Some States have developed programs that help seniors better access these programs as a partial solution to helping them obtain their needed medications. Here in Florida we have the Silver Saver Program, which provides $160 a month in prescription drug benefits to about 58,000 elderly Floridians who are Medicare eligible and have family incomes between 88 to 120 percent of the Federal poverty levels. Silver Saver does not have an enrollment fee, membership fees or any other monthly fees. There is only a small copayment system: $2 for generic drugs, $5 for drugs on the State's preferred drug list and $15 for those drugs not on the preferred list. The Silver Saver benefits could cover the cost for up to as many as nine prescription drugs a month.

In summary, let me once again say that Navarro Discount Pharmacies and its pharmacists are sympathetic to the plight of seniors who are trying to afford their medications. We do not think that obtaining drugs from international sources is safe or reliable, and we caution our seniors against it. Moreover, there are already a number of programs available to seniors that will help them obtain their prescription drugs at more affordable prices. We again thank you for holding this hearing, and I look forward to any questions you have.

[The prepared statement of Carlos A. Ruiz follows:]

PREPARED STATEMENT OF CARLOS A. RUIZ, DIRECTOR OF PHARMACY, NAVARRO DISCOUNT PHARMACIES

Mr. Chairman and Members of the Subcommittee. Let me welcome you to Miami. I am Carlos A. Ruiz, Director of Pharmacy for Navarro Discount Pharmacies, based here in Miami. We operate 16 pharmacies throughout the Miami-Dade and Broward county areas. Last year, we filled over 1.7 million prescriptions and we employ over 1,300 Floridians.

We very much appreciate you holding this hearing on issues relating to imported prescription pharmaceuticals. In my statement today, I want to talk about the importance of patients having access to the local pharmacy, and why reimportation can be dangerous for consumers. I also want to talk about programs that already exist in this country that help seniors with their medication purchases that do not require them to look across the border for help.

When a patient arrives at their local community pharmacy, be it a chain pharmacy or an independent, they come into contact with one of the most accessible and trusted providers in the entire health care system. It is estimated that 95 percent of Americans live within five miles of a retail community pharmacy. For almost 20 years, surveys show that pharmacists are among the most trusted health care professionals.

Thus, the vast majority of Americans are never far from a highly trained health professional who can provide medications or advice on a wide range of health care issues. Convenient access to community pharmacies makes us a critical part of society's health care safety net.

Prescription medications are the most widely used and cost-effective health care interventions used by patients today. Modern prescription drugs have extended and improved the lives of millions of Americans and saved millions of dollars through

shortened length of illnesses, increased productivity, and reductions in hospitalization and medical procedures. Community pharmacy is proud of the role we have in assuring the safe and effective use of these therapies.

Every day, our pharmacists see seniors struggling to afford their prescription medications. We get many questions from seniors about how they can buy their drugs from Canada and other countries where prescription drugs might be less expensive. It is true that the prices for drugs in Canada and other countries are less expensive than those in the United States. These comparisons are inevitable. We have also seen a drop off in business in some of our pharmacies because of the growing illegal reimportation trade going on, especially in the state of Florida where there is a large senior population. However, we discourage seniors from obtaining their drugs through these methods because the drugs they receive might be counterfeit, of impure quality, or simply not the drugs that they are supposed to be.

Moreover, foreign-imported drugs do not have the important safety and quality checks that are built into the current U.S. community-pharmacy based distribution system. Seniors also do not receive face to face counseling or medication management from pharmacists by purchasing drugs from these international schemes, potentially jeopardizing their life and health.

There are other legitimate ways for seniors to obtain medications without having to subject themselves to these potential safety and quality problems, and I am here today to discuss these approaches. I can offer many anecdotes to the Committee of patients that come into our pharmacies who cannot afford their medications. Some of these stories are heartbreaking. What can pharmacies do to help these seniors obtain their prescription drugs?

Encourage Generic Use: First, our pharmacists work with patients and their doctors to try to maximize the use of lower-cost generics when they are available on the market. The savings from using generics are unmistakable. At Navarro, the average brand name prescription price is about $65, while the average generic prescription price is about $16, a difference of close to 400 percent.

Obviously, if a generic substitute is not available, we will try and work with the doctor to see if the patient can, in fact, take a generic version of another drug or a less expensive therapeutically equivalent branded drug. With billions of dollars in brand name drugs coming off patent over the next few years, we believe that it is critical that seniors have incentives to use generics. We will also try to help patients use a less expensive over the counter medication if they cannot afford their prescription drugs. These OTCs may not work as well as the prescription versions, but the choice for patients sometimes comes down to taking something that may not work as well, or nothing at all.

Senior Citizen Discounts: Second, many of Navarro's pharmacies also offer discounts to senior citizens on their prescription drug purchases. Navarro is a deep discount pharmacy. Most pharmacies in general offer discounts of about 10 percent, but each pharmacy has its own policy on discounting their prices for seniors. Some pharmacies have their own arrangements with other groups and entities to offer prescription discounts. For example, we work with a group called "Liga Contra el Cancer" to offer prescription discounts to cancer patients who cannot afford their medications. We also work with church organizations, such as St. Vincent de Paul, to assist them in providing low-income or indigent patients with needed medications they cannot buy.

Consumers already reap the benefits of the highly-competitive retail pharmacy marketplace. We are a fiercely competitive industry, as evidenced by our 2 percent net profit margins. If you do not like the price at one pharmacy, you can go to another. Many pharmacies will match their competitors' prices. And yes, retail pharmacy prices do vary store to store, reflecting differences in the cost of doing business, loss leaders, and other factors. The fact is, consumers can and should shop around for the most favorable prices for their prescriptions. You should know that pharmacies do not have much, if any, margin in the prescription drug business. Yes, the costs of drugs are high, but that is primarily due to the high costs of buying prescription drug products from the manufacturers.

Manufacturer Patient Assistance Programs: Third, we can help the poorest seniors access the patient assistance programs that pharmaceutical manufacturers have established. Clearly, these programs provide a short-term benefit to some low-income seniors, but they are not an adequate solution or appropriate substitute for meaningful, long-term prescription drug coverage. Almost all pharmaceutical manufacturers have established assistance programs that provide free prescription drugs to patients, including senior citizens, who do not have the resources to obtain their medications.

These programs usually require that the patient's physician certify to the manufacturer that the patient does not have the resources to obtain their prescriptions.

Many low-income seniors forgo taking their medications because they do not have the resources to purchase them, but remain unaware that such programs exist. The Pharmaceutical Research and Manufacturers Association (PhRMA) has a website, describing these manufacturer-based programs, which can be found at www.phrma.org. Eligibility standards and benefits vary among manufacturers. Also, the complex enrollment forms can make accessing these programs challenging. Several states, however, recognizing the positive impact that these programs might have on helping seniors obtain prescriptions, have taken action to educate them about these programs and simplify the enrollment process.

Manufacturer-Pharmacy Discount Programs: A relatively new program, called Together Rx, offers significant discounts to low-income seniors on the purchase of their medications. Under this program, manufacturers and pharmacies have joined forces to offer seniors discounts of up to 40 percent on almost 150 popular brand name prescription medications. At Navarro, we have gone a step further and offer discounts on generic medications as well. These prices are as good in many cases as the prices that seniors would pay for drugs from Canadian sources. These discounts are passed along to seniors at the pharmacy counter. Over half million seniors have enrolled in the Together Rx program since its inception, saving $3.2 million for seniors each week, or about $32 million to date.

Other manufacturers have developed programs for low-income seniors that only require that they pay a flat fee for their prescription drugs. For example, under the Lilly Answers program, low-income seniors only pay $15 for a 30-day supply of most Lilly outpatient brand name drugs. Pfizer has a similar program, charging $12 for a one-month supply of many of their outpatient medications. Seniors can find more information by clicking on www.togetherrx.com. Navarro participates in this program and we view this as a model for a potential Medicare drug benefit for seniors.

State-Based Assistance Programs: Some states have developed programs that help seniors better access these programs as a partial solution to helping them obtain their needed medications. Here in Florida we have the "Silver Saver Program," which provides $160 a month in prescription drug benefits to about 58,000 elderly Floridians who are Medicare eligible and have family incomes between 88-120 percent of the federal poverty level (between $7,797-$10,632). Silver Saver does not have an enrollment fee, membership fees or any other monthly fees. There is only a small co-payment system: $2 for generic drugs, $5 for drugs on the state's preferred drug list and $15 for those drugs not on the preferred list. The Silver Saver benefits could cover the cost for up to as many as nine prescription drugs a month.

CONCLUSION

In summary, let me once again say that Navarro Discount Pharmacies and its pharmacists are sympathetic to the plight of seniors who are trying to afford their medications. We do not think that obtaining drugs from international sources is safe or reliable, and we caution seniors against it. Moreover, there are already a number of programs available to seniors that will help them obtain their prescription drugs at more affordable prices. We again thank you for holding this hearing, and I look forward to your questions.

Mr. GREENWOOD. Thank you, Mr. Ruiz.

Mr. McEwan.

TESTIMONY OF ROBERT N. McEWAN

Mr. MCEWAN. Thank you, Mr. Chairman, and thank you for inviting me today to speak before your committee. I would step back from the written testimony that I provided because much of it has been covered by today's discussions and talk to you about the programs that are there for the asking provided that you have someone that is called a patient advocate. I think that for the examples of the patients that were here today, if they had had an active patient advocate, all but one of the drugs in the programs of the ones they described are available through pharmaceutical Patient Assistance Programs.

Let me step back just a little bit to tell you that from the beginning I have been working in science and medicine and health care for my entire career now. And the one thing that flows through

that entire career path is the one thing they teach in medical school, and that is first do no harm. And I think that it is always put the patient first, and it is shared by physicians, it is shared by pharmaceutical industry, it is shared by pharmacists and it is shared by health care advocates throughout the country. And the one thing that happens as a consequence of not being able to get help is just like water here in Florida can do a lot of damage in a short period of time, it finds the path of least resistance. And the solutions for these patients that cannot afford their medications by the things that you are hearing about today—Internet sales and black markets and so forth—are all finding the path of least resistance.

But truly there are solutions out there that are broad in scope that will cover just about every example of every patient. And I say that because I started out from the situation in a transplant center here in the United States that basically recognized that there was a black market going on between patients. I mean here we had patients who were changed from drug A to drug B and they basically had drugs that were not expired, that were still seemingly active, passed from patient to patient as a means of trying to help those patients that couldn't afford their drugs. And I said even though on the face of it that might have seemed like a safe practice, it wasn't. Somebody had to take ownership of the situation and say, "Enough. We have to do this legally, we need to do this right."

I mean when a patient's drugs were passed from patient to patient, for example, there was never any discussion of whether they were in the trunk of your car when you drove through the desert and the heat in your trunk reached 1000 degrees and inactivated all your drugs, and that is the reason why they didn't work for you, and that is why your doctor was now switching you to something else. You may have just passed the problem off to someone else. So by owning the problem and becoming an advocate for patients, I have actually left the transplant center scenario right now and now represent an entire State who is taking a centralized approach to advocacy for its patients.

Basically, what you have heard described all day today is a patchwork quilt, if you will, of the solutions for pharmaceuticals to patients nationwide, and they all work at various levels. At the highest level, there is obviously Medicaid and pharmacy assistance programs that are available in some States. The need, though, for a more specific and generalized pharmaceutical assistance support nationally is clearly what is needed, because if the patients had a choice between going through the Internet, between going through a black market or any other mechanism which required paperwork, which asked questions that were very personal to them, they would obviously take them through a prescription plan that offered coverage like a Medicare prescription plan would.

But they don't have that now, and so in its place we create this matrix. And the matrix starts at the highest level and says do you qualify here? No, you don't? Okay. Then you come to this level. Do you qualify here? Well, here, you are only on a few drugs, so maybe we can get you help for the drugs here best through just having you get a prescription card, like Together Rx or Lilly's Answer or something like that. But each step of the process is carefully

triaged by someone called a patient advocate, and we decide with the patient whether that is going to be their solution.

Now, if you take our State, for example, we have gone from having only 2,000 patients helped by our program to over 20,000 in 2 years, and we are enrolling patients at a rate of just under 1,000 a month. And, basically, these patients when they come in are getting help going through this triage. We work on behalf of the physicians, because we want them to get the medicine to the patients. And in fact after 2 years of operation, we did a little study on our patients, and we said of these patients who have received their drugs from the pharmaceutical Patient Assistance Programs for at least 180 days, what was the effect on their health care, their subsequent health care? And we found that 52 percent of the patients had had decreased hospitalizations; 62 percent of the patients had had decreased emergency room visits. And we then were able to document improvement in blood pressure, improvement in blood sugar and a lot of the diagnostic parameters or clinical parameters that a physician would do to say, yes, these medications are working.

And exactly what we would have predicted is what we got, that in fact where we are bringing in $1 million a month to our program for our patients, which they receive free without any dispense fee or anything else, the actual translation to our State is roughly—well, we are bringing in $1 million a month, it is roughly 6 to 7 times that amount in savings to the health care system through uncompensated care, through patients that don't show up with—aren't admitted with unscheduled hospitalizations. Emergency rooms in urban areas, for example, are used as primary care centers, and the emergency rooms are flooded with these patients that basically are in there for their primary care because they are not properly medicated. We can keep them out of those emergency rooms, we can keep them out of those hospitals, all much more expensive options if they don't get their medications.

So what I would tell you about is the fact that in the pharmaceutical industry they provide——

Mr. GREENWOOD. I am going to ask you to sum up in 1 minute, please, if you would.

Mr. MCEWAN. Basically, $2.3 billion worth of drugs reached 5.5 million patients, by their own statistics. And the take-home message is this: That to the people who told me not to start MEDBANK because the minute you were successful the pharmaceutical industry would pull the cord on it and do away with it because they would see it eroding their profits, I don't see that happening. I see companies staying on board, I see companies facilitating my success every day at reaching patients. And I think central to the whole idea of being successful in the patient environment is having a patient advocate that can help anybody of any age through any circumstance triage the system.

[The prepared statement of Robert N. McEwan follows:]

PREPARED STATEMENT OF ROBERT N. MCEWAN, CHIEF EXECUTIVE OFFICER, MEDBANK OF MARYLAND, INC.

For eighteen years I worked as a scientist at the bench in labs in government, in academia, and in the pharmaceutical industry at the Upjohn Company. The years I spent at Upjohn were in a state-of-the-art biotechnology research division that did

cutting-edge research in molecular and cellular biology. One of the things that was gratifying to me as I worked at the bench was knowing that the company, indeed the whole industry, did its best to make medications available to those who could not afford them. They did so through what they called Patient Assistance Programs (PAP). What I did not know back then was that at some point in the future, I would become very intimately engaged with these programs.

I left research and went into marketing and sales in Upjohn and it was there that I saw these Patient Assistance Programs in action, first-hand. I emphasized to all the community physicians I called upon that free prescription medicines were available to patients who could not afford them. I would often see the stock bottles sent by various pharmaceutical companies including my own, on the physicians' shelves, just waiting to be given to the patients who needed those medicines. Today, the pharmaceutical industry's Patient Assistance Programs are more sophisticated, and continue to be there for patients in need. The programs are designed for patients without prescription drug coverage and annual incomes below 200% of the Federal Poverty Level or roughly $18,000.

As my career in health care continued I found myself at one of our country's leading hospitals running its transplant center. Again I learned first hand what it meant for individuals to go without valuable medicines when I saw patients die. Some of the patients were ashamed that they couldn't afford the medicines they were prescribed, but today I am here in Florida to let Florida residents know that help is available for those in need.

Patient Assistance Programs are running strong. In the last year alone, the research-based pharmaceutical industry gave out over $2.3 Billion worth of medicines to patients who could not afford them, helping over 5.5 million patients. This translated to an estimated 223,000 Floridians receiving free medicines in just 2002. By anyone's standards that is great charity.

So why are the pharmaceutical companies continually attacked when they are doing so much good for American patients and providing so much to Americans with little means? Because the crowd of people who need assistance is growing faster. The need is being driven by the huge number of "baby boomers" that are approaching or are in their 60's and simply due to the incredible advances new medicines deliver. There was a time when patients who were sick were relegated to missing time from work, or being hospitalized, or maybe even worse. Today new medicines have the ability to keep people of all ages active at work, at home and out of the hospital. So clearly, demand for medicine has grown over the last twenty years because many new prescription medicines have delivered marked improvements to patient health.

For Florida residents in need of medicines, there are 136 Patient Assistance Programs and over 10 discount drug cards alone sponsored by the research-based pharmaceutical industry today. And, we are constantly looking for new and better ways to get medicines to patients. A Patient Assistance Program sponsored by the generic companies could provide additional medicines to patients. Currently, these programs are only available from the brand name companies.

For Florida residents without drug coverage at roughly an annual income of $18,000 or less, PAP programs are a solution to obtaining the medicines they need. In fact, there is now a new on-line database that Florida residents can take advantage of to access user friendly information about more than 1,400 medicines offered free through patient assistance programs. The on-line database is sponsored by the Pharmaceutical Research and Manufacturers of America (PhRMA). Florida residents who need help in obtaining medicines can log on to www.helpingpatients.org, fill out an online form and receive a list of programs for which they may qualify. For those without access to the Internet, they can call 1-800-762-4636 to obtain a copy of the directory of patient assistance programs.

Additionally, for Medicare beneficiaries living in Florida of slightly more means say $30,000 for an individual or $40,000 for a married couple, a solution can be found once again within the research-based pharmaceutical industry in the form of Seniors Savings Card programs like Together Rx. Together Rx is available free of charge with an easy sign-up process and makes more that 150 medicines available to an enrollee at discounts from 25 to 40 percent. This program has already resulted in $36.7 million in savings for cardholders, and now is providing discounts to over 600,000 beneficiaries across the country. Similar programs, such as the Pfizer Share Card and the LillyAnswers Card provide 30-day supplies of medication for a $12 or $15 fee for individuals with an annual income below $18,000, or $24,000 for a couple.

The options don't end there for those who that cannot afford medications. A skillful shopper can find within the same city the most expensive place to buy their medications and the cheapest. In fact, a study conducted by the Florida Council on

Aging found that retail prescription drug prices vary as much as 683 percent for certain medicines from pharmacy to pharmacy across the State of Florida. The difference in shopping around for the best price for a particular medicine can save consumers real money. Buying medicines isn't really any different than buying groceries so it is important to remember that sometimes it helps to shop around a bit.

In Florida specifically, there are helpful statewide programs like the Florida MEDS-AD program and the Silver Saver program which provide savings and safety nets directed at the elderly and the disabled in Florida. Florida's Silver Saver program, named after retiring Senator Ron Silver of North Miami, serves about 58,000 elderly Floridians who are Medicare eligible and have family incomes between 88 and 120 percent of the Federal poverty level ($7,797-$10,362 a year). It does not have an enrollment fee, membership fee, or any other monthly fee and has only a small co-payment, between $2 and $15 per prescription and provides $160 a month in prescription drug benefits for those eligible.

Mr. Chairman, Florida residents are looking for solutions to their medical problems. Many of those solutions can be found in the programs established by the research-based pharmaceutical industry. These solutions are very cost-effective when compared to other options such as hospitalization or surgery. And, these solutions are also much more preferable for Florida residents than subjecting themselves to medicines of questionable origin when looking for the "quick fix" on the Internet or on trips to Canada or Mexico.

All of these programs will help Florida residents; but, the most significant help will come in the form of a meaningful Medicare Prescription Drug Benefit passed by Congress. And, one that keeps investment in research & development robust and protects the hope for future cures. I understand that the President has pledged 400 billion dollars to provide this benefit. Now is the time for Congress to act on this and do right by Florida's seniors.

Florida patients have been very outspoken about the life-saving value of the Patient Assistance Programs. Patients like Terence Stevens in Lakeland, or Steve Kersker in Tampa, who are just two of the more than 232,000 Floridians who are grateful to the pharmaceutical industry for these programs. But these numbers don't reflect the human side of these programs. Just the other day, a woman called to tell me that her husband had been averaging 2-3 trips per month in an ambulance to save his life because of an untreated heart condition—untreated because they could not afford his medications. Today that same man has not been near a hospital in months, and it is all because of the drugs he takes (not generic by the way) but new, cutting edge medicines given to him free of charge by the companies that discovered them.

I'll end this testimony by saying that my father, who died at 54, would have been here today if he had today's advanced medicines. My mother who died of emphysema would have known relief longer into her years if she had benefited from today's medications.

I thank Chairman Greenwood and Congressman Deutsch for the opportunity to speak before the subcommittee.

Mr. GREENWOOD. Thank you very much. We have precisely 15 minutes left for this hearing, so each of us will take 5 minutes, and we will keep it to a tight schedule here. And I thank each of you. I thank each of you for your testimony.

Mr. McEwan, let me understand since you departed from your written testimony, just give us a quick and dirty on what MEDBANK is, who pays for it and how it came to be.

Mr. MCEWAN. Right. We started out 3 years ago with a small grant from the Maryland Health Care Foundation to cover a city and a county.

Mr. GREENWOOD. That is a private foundation?

Mr. MCEWAN. Yes. And MEDBANK of Maryland is a 501(c)(3), as is our MEDBANK Pharmacy now is a non-profit pharmacy. And, basically, in its second year of existence we were able to convince our legislature that we were going to be able to do a significant good within our State if they wold fund the infrastructure for these patient advocates Statewide. We have satellites all over the State of Maryland as well as a centralized data base that——

Mr. GREENWOOD. So the State of Maryland is now covering your costs?

Mr. MCEWAN. That is right.

Mr. GREENWOOD. And what are those costs?

Mr. MCEWAN. The cost of the infrastructure for the entire State is $2 million a year.

Mr. GREENWOOD. And what do you figure per client benefit or for senior benefit or some per capita or per prescription assistance? How does the cost break out that way?

Mr. MCEWAN. The cost is somewhere between $75 and $80 per patient.

Mr. GREENWOOD. Per patient, okay. And that compares with how much money that you are saving the patient directly versus some of the indirect costs you talked about.

Mr. MCEWAN. Right. The savings to the patient—our average patient is 60 years old, our average patient is on 7 medications, and our average patient is of an income of $1,300 a month. So you take all these things together and you are basically saving the patient thousands of dollars per year. And this is a per year cost.

Mr. GREENWOOD. Let me describe the current situation of two south Florida seniors. I would like you to tell me whether these individuals qualify for any of the plans that the pharmaceutical companies sponsor and whether they can get their medications free or at a greatly reduced cost.

The first senior receives under $10,000 a year in Social Security. He is taking the following medications: Accu-Chek, Urabid, Glucotrol, Allopurinol, Warfarin, Dytoxin, Toprol, Glucophage, Zocor, Quinine Sulfate, Oxycodeine and Flonase. And I assume that that represents Mr. Sweed's circumstances.

The second I believe describes Ms. Coplan's situation. She has an annual income of approximately $23,000. She is taking the following medications: Singulair, Fosamax, Verapamil, Zanax, Atrian and Tramadol. And I believe you have done a bit of an analysis of how you think they could benefit from a patient advocate, if you will, and gaining access to these other programs.

Mr. MCEWAN. Okay. In my program, if I were looking at the first patient that you mentioned, essentially that patient would qualify immediately.

Mr. GREENWOOD. Make sure you pull your microphone up close to you and speak directly into it, because there is particular interest in what you have to say now.

Mr. MCEWAN. From the first patient you asked about, Accu-Chek is the monitor that he uses, and the question there is whether strips are available I think is usually the question. We haven't found any organization or company yet that provides these strips free, so the dollar a day for those strips to be monitored is probably an out-of-pocket cost that we can't get around. Of all the remaining drugs that that patient, Mr. Sweed, is taking, the only one that I could not find a program for was Aloprinol, and I am sure that if I were to get with a physician, I could probably find a substitute. And this is an important thing to realize. Through web sites like helpingpatients.org, the new PhRMA web site, the patient can put this information in themselves. They can put in their income, their

age and so forth, and it will tell them if there is a program for them.

The other thing is is that we use—obviously, we use technology as well, and Volunteers in Health Care has a web site called Rx Assist that I can go in there and I say, okay, the patient doesn't have one of these drugs available through a PAP, so the class of drugs that that drug is in are there any other programs? So you pull up the class of drugs, and you will get 5 or 6 alternatives. So now you call this doctor and you say, "Would any of these others work, and if so, would you give the prescription and dosage so that we can continue to get their medications free?" This is very important because these drugs do come and go, and as the go, we need to find replacements for them. As sometimes they become in short supply, we need to find replacements for them. So we use technology, basically, to stay on top of this.

We have within our web site, of our data base that we market to other States right now, Rx Bridge, a separate link to something called Brave Pages, which we update. It contains all the information in this book, for example, that tells you about every single company, what the requirements are, what the income limits are and so forth so that as a patient advocate is working they can get ready access to information. So that would take care of the first patient. The one drug would be singled out that would need further investigation.

The second one, at a little bit higher income level, still qualifies for most PAP programs, I feel confident, although I have no way of saying that it qualifies for all of them just as a blanket statement. Every one of these programs' income limits are kept within that companies' rights, and, essentially, where it is advertised, we know immediately, where it is not, we don't. Of the drugs that that patient is taking, the only one which does not have a program currently is Zanex, and for that we could substitute, if the physician agrees, valium, which is available through a PAP with the Roche Laboratories.

So there are choices and opportunities. It takes advocates that are smart about the whole process and understand the drugs well enough to be able to make these informed counsels.

Mr. GREENWOOD. Okay. Thank you. I think you know Ms. Coplan, she is in the back, and she has been cupping her hand and listening intently, so if you could chat with her before you leave, I would appreciate it. And it seems to me that the service that you provide we in the Congress would do a heck of a lot of good if we could figure out how to make that kind of service available to everyone in this country, because no matter what we do with prescription drugs in terms of a benefit for Medicare, we are not going to cover first dollar for everybody, there just isn't that much money in the world. Patients are still going to need to be able to find assistance outside of the Medicare program to get the best value for their dollar.

Mr. MCEWAN. That is an excellent point because in our program alone 56 percent of our patients are not Medicare.

Mr. GREENWOOD. Right.

Mr. MCEWAN. And they all get benefit.

Mr. GREENWOOD. The gentleman from Florida for 5 minutes.

Mr. DEUTSCH. Thank you, Mr. Chairman. And I would actually just follow up and completely agree with the last point you made. In a perfect scenario, which obviously most of us know in the human condition there are very few perfect scenarios, we will not—the bill we pass hopefully this session won't be implemented for 2 or 3 years at the absolute earliest; there will be a phase-in period. So real people are faced with these real problems today. And I think this panel's purpose really is to try to attempt to deal with some practical solutions that people have.

One follow-up question, though, for Mr. McEwan. Could you mention that web site again and who the sponsor of the web site was?

Mr. MCEWAN. There is a PhRMA web site now called helpingpatients.org., and that new web site allows you to put in the actual drug you are asking about, it allows you to put in your patient circumstance, and it will say, yes, there is a program for you, here is where you get more information.

Mr. DEUTSCH. And as your experience been based upon your sort of expertise versus the web site, how good are they compared to you, the web site?

Mr. MCEWAN. Their web site just started up, and what we provide beyond what they provide is that all of the forms for all of the pharmaceutical industry PAP applications are linked online on our data base so that they will be printed out with all the patient information and passed over to the physician for signature. This is what we recognized was the problem, that you are not just applying for one or two drugs on behalf of the patient, you are applying for 7 or 8 and so——

Mr. DEUTSCH. I am going to move along because actually we are going to try to keep this 5-minute timeframe, because I know the chairman actually has a flight he is trying to catch.

Mr. Hahn, in Mr. McEwan's written testimony, he made a remark, and I am quoting, "A Patient Assistance Program sponsored by the generic companies could provide additional medicines to patients." You talked a little bit about it but if you could elaborate in terms of generic companies, do they have the resources to build these assistant programs or the benefits of assistant programs already reflected in generic drugs' cheaper prices?

Mr. HAHN. Well, I know that at Andrx we have offered drugs to indigent patients free of charge. With respect to overall program, I don't think we have a specific program in place, but it is done as patients contact us in particular for specific drugs, and cardiovascular drugs would be one I am very familiar with. With respect to Altocor, I am not sure that we have implemented it yet, because we have only launched Altocor in August/September of last year. However, we have been in contact with an organization that represents, I believe, at least 60 physicians in the New York area where we are talking about giving them Altocor free of charge to indigent patients.

Mr. DEUTSCH. The public seems comfortable using generic drugs as a less expensive alternative to high-price branded pharmaceuticals. Can you explain how your technology gives the consumers the added value you mentioned in your testimony?

Mr. HAHN. Yes. Administering a drug once a day, which is what our technology is designed to do, as opposed to giving a drug two, three or potentially four or more times a day, allows for enhanced compliance by the patient. And, obviously, compliance will lead to the end point you want, that you treat the disease state or achieve the required therapeutic end point, especially with the aging in the population where it has been mentioned by others patients are on multiple drug therapies. They have to remember do I take my pink in the morning and evening, my blue pill in the morning and afternoon or my yellow pill in the afternoon and evening? Once a day makes that a lot easier for them to do.

Second, we potentially can enhance the efficacy and safety of the drug with our drug delivery technologies. The benefits are obvious there. And, third, as a result of our dealing with known and safe drugs, we can utilize a process within the new drug applications within the FDA that allows us to develop these products in a more timely and cost-effective manner, and therefore we can provide these savings that we achieve in the cost of developing these drugs and pass them on to the consumers.

Mr. DEUTSCH. Let me jump to both people representing the actual pharmacies in Florida today, and I think you elaborated very well what you can do for individual patients coming up to you. If you can give us some—any additional insight in terms of the proliferation of the foreign pharmacies, for lack of a better word. I assume you have gone to the State—you heard testimony by Mr. Taylor earlier. In terms of your interaction with the State, I mean your position, I think you have stated, is that they are illegal at the present time. Are you trying to do something to force enforcement of action that the State could in fact take at the present time?

Mr. JACKSON. Yes, Congressman Deutsch. We have as an association visited with our State's regulatory board and have discussed this issue intently. Members of the board are pretty much in agreement that there is unlicensed, unregulated activity out there. If you ever had an opportunity to review and take a look at the regulations affecting the practice of professional pharmacy——

Mr. DEUTSCH. Right.

Mr. JACKSON. [continuing] you will find that it is fairly extensive, and these entities are operating really in a void, in a vacuum.

Mr. DEUTSCH. But, again, they are operating publicly, they are advertising publicly, I mean they are extensively advertising at the present time. I mean why they are existing?

Mr. JACKSON. Well, I think they are trying to serve a need.

Mr. DEUTSCH. No, no. But I mean in terms of the regulatory side. If you are saying that from the regulatory side they should be shut down, why have they not been shut down?

Mr. JACKSON. Well, Congressman, I really don't know. That is something our State regulatory initiatives are looking at right now. And they are communicating with us, letting us know what it is they are doing.

Mr. DEUTSCH. Can I just follow up again, I mean both with you or Mr. Ruiz if you can. Is the sort of market price—because, obviously, there are some consumers who are aggressively shopping. They are either calling you and going to you, going to Costco, looking at cards, really trying to get the best price, especially if it is

a drug they are going to be taking continuously. I mean is the floor price now the Internet pharmacy price, the foreign pharmacy or your price? I mean where is the floor price? I mean is your competition literally now those entities in terms of the price that you have to charge or, as you said, in some cases you might be a better price?

Mr. RUIZ. In all honestly, I don't think that we in retail pharmacy can provide the floor price. We cannot buy prescription drugs at the prices that either international site are selling at or Internet sites. Again, our primary concern is for our patients. I am going to talk as a pharmacist, I am not going to talk as an administrator. Patients come in every single day, 10 prescriptions, they have to take multiple drugs at different times. Sometimes they can't even afford the co-payments. I mean we are not talking about actually the paying the out of pocket, I am talking about being able to pay——

Mr. DEUTSCH. The $5 co-pay.

Mr. RUIZ. [continuing] 10 drugs, $15, that is a $150 a month——

Mr. DEUTSCH. Right.

Mr. RUIZ. [continuing] for somebody who probably lives on a fixed income. Are we opposed to them getting low-cost medications? Absolutely not.

Mr. DEUTSCH. Right.

Mr. RUIZ. I mean what is the point to—and I would prefer that they get their medications even if it is somewhere instead of them not taking it at all. And, of course, the main concern is, well, if you are going to an international site, if you are going to the Internet, who is looking out for your best interest in terms of drug interactions——

Mr. DEUTSCH. Let me try to jump in one last question. Back to Mr. McEwan. I think all of us are very impressed with the program that you have set up and I am going to at least check the site and play around with it a little bit. If that is an ancillary use, maybe even we will do some further oversight at your actual agency. Because at a practical level, it seems people can avail themselves of something today. But even if it exists, why—I mean is it just people aren't aware of it? I mean the access point in terms of so many people using Canadian drug—I mean how would you explain the phenomenon if this is all available. If the cards are available and the discount plans are available and all these options are available, why are—you had 20,000 people, great. We have got 10 million people doing it another way. I mean just the scale—I mean very few—I mean relatively very few people are accessing your system.

Mr. MCEWAN. None of Florida's patients, for example, are able to access the Maryland system, because being paid for by Maryland it has to only have Maryland patients, but every State could have a MEDBANK, and some States do have MEDBANK equivalents. There are other States that have centralized patient advocate organizations that do what we do, and we do it to the extent of creating field guides for how to set it up, we have a data base that we market to other States, and we go over backwards to basically try to teach people how simple it is. But it does take some infrastructure, it does take some investment.

Mr. GREENWOOD. The Chair thanks the gentleman. The gentleman from New York for 5 minutes.

Mr. ENGEL. Thank you, Mr. Chairman, and I will be brief because I know time is of the essence. I just really have one question to sort of tie this together. Perhaps Mr. Jackson or Mr Ruiz or both could answer it.

My concern, we have heard the other panels and obviously it is a very bad choice for consumers, for senior citizens who are finding it increasingly difficult to pay for skyrocketing prices of drugs. What about the pharmacies, though, that are playing by the rules? You know, you are playing by the rules, you are getting medications that are safe, and in essence you are being undercut by people buying these drugs from dubious places around the world. We don't know how safe they are and so on. What is happening from an economic perspective to pharmacies? Since you don't buy your drugs from foreign sources, at some point might there not be a point where you are not competitive, you may be forced down the line to go out and buy your drugs from foreign sources? Mr. Jackson, you said that pharmacists and pharmacies in Florida are being harmed by the walk-in international pharmacies. Perhaps we can start with you, and then perhaps Mr. Ruiz can tell us as well.

Mr. JACKSON. Okay. Thank you, Congressman Engel. Our members have reported to us that for some strange reason that their businesses are starting to flatten out, and they can't really point a finger as to what could be causing that. Usually, when a pharmacy loses business or has a flattening of business, they can get a feel for what is happening, and it could be a situation where a patient, for whatever reason, chooses to use another pharmacy provider because they have changed an insurance plan or it could be because of competitive pricing they elect to go to a different competitor. But you can track that because records from the dispensing pharmacy has transmitted to the new pharmacy, and so you can see where your business is going when those types of events occur.

But under this type of scenario patients are just exiting or not coming back to the pharmacy because they have chosen an alternate provider, and that is difficult for a pharmacy to track. When a pharmacy begins to lose business in this way, then just like any business, they have to do things internally to try to compensate for that, such as reduction in services, lowering office hour times, cutting out prescription delivery services to patients that are unable to ambulate and many other things that they would have to do internally to try to meet their own operating expenses.

Mr. ENGEL. Mr. Ruiz, anything to add?

Mr. RUIZ. Yes. One of the things—certainly, any time that business decreases, and, again, you can track it by checking whether it is going to your competitors or not, pharmacists are in short supply. Pharmacists salaries are very competitive. It is difficult to retain pharmacists and be able to provide these services to our patients if we are not able to at least continue to make those minimal margins that we are making. It makes it pretty difficult to continue to operate. Obviously, the larger chains and possibly some of the independents that have been around for quite some time are not going to be impacted as much immediately, but at least as far as the independents, they cannot withstand those drops in businesses.

Mr. ENGEL. You know, if you have an airline, for instance, that doesn't maintain its planes, of course it would be able to sell its tickets at a cheaper rate, and obviously that is what is happening from these walk-in international pharmacies, so it is certainly a major concern.

In the interest of brevity, Mr. Chairman, I am going to stop here, and I thank you for giving me the opportunity to participate.

Mr. GREENWOOD. The Chair thanks the gentleman. Thank yo to all of our witnesses. Thank you to all of the witnesses throughout the hearing. We thank the city of Aventura for its hospitality, thanks to the stenographer, to the staff on both sides of the aisle here, to all of you for coming, and thanks mostly to Congressman Deustch for his leadership in this issue, as well as in so many others. This hearing is adjourned.

[Whereupon, at 1:40 p.m., the subcommittee was adjourned.]

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